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ORIGINAL

CONSUMER PRODUCT SAFETY COMMISSION'S RESPONSE TO HAZARDS OF THREE-WHEEL ALL-TERRAIN VEHICLES [ATV'S]

FORTIETH REPORT

BY THE

COMMITTEE ON GOVERNMENT OPERATIONS

together with

ADDITIONAL AND DISSENTING VIEWS

JULY 16, 1986.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

U.S. GOVERNMENT PRINTING OFFICE

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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
Washington, DC, July 16, 1986.

Hon. THOMAS P. O'NEILL, Jr.,
Speaker of the House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: By direction of the Committee on Government Operations, I submit herewith the committee's fortieth report to the 99th Congress. The committee's report is based on a study made by its Commerce, Consumer, and Monetary Affairs Subcommittee.

JACK BROOKS, *Chairman.*

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99TH CONGRESS
2d Session

HOUSE OF REPRESENTATIVES

REPORT
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JULY 16, 1986.—Committed to the Committee of the Whole House on the State of the Union and Ordered to be printed

Mr. BROOKS, from the Committee on Government Operations, submitted the following

FORTIETH REPORT

together with

ADDITIONAL AND DISSENTING VIEWS

BASED ON A STUDY BY THE COMMERCE, CONSUMER, AND MONETARY AFFAIRS SUBCOMMITTEE

On June 24, 1986, the Committee on Government Operations approved and adopted a report entitled "Consumer Product Safety Commission's Response to Hazards of Three-Wheel All-Terrain Vehicles [ATV's]." The chairman was directed to transmit a copy to the Speaker of the House.

I. INTRODUCTION

Under the House of Representatives Rule X, 2(b)(2), the Committee on Government Operations is authorized to "review and study on a continuing basis, the operations of Government activities at all levels with a view to determining their economy and efficiency." The committee has assigned this responsibility, as it pertains to the Consumer Product Safety Commission (CPSC), to the Subcommittee on Commerce, Consumer, and Monetary Affairs.

Pursuant to its authority, the subcommittee conducted an oversight investigation of the CPSC's response to the hazards of all-ter-

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rain vehicles (ATV's).[1] The subcommittee set out to examine the Commission's response to the unprecedented level of deaths and injuries which have accompanied the increased popularity of these vehicles. It also examined the response of the manufacturers of ATV's and the role of the States in regulating their use.

The subcommittee's study dealt primarily with three-wheeled ATV's. This report therefore does not make any findings or recommendations relative to four-wheeled ATV's.

The most significant safety-related fact about ATV's is the unprecedented level of deaths and injuries associated with their use and the rapid increase in the rate of these casualties since the problem first became known to the CPSC. At least 415 people are known to have died in ATV-related accidents since 1982, with the death toll increasing dramatically each year. By one estimate, four to five people will die every week this spring and summer if the death rate for these months of heightened ATV use continues at last year's pace.[2] In 1985 alone, the CPSC has reports of 174 deaths, with more yet to be counted since there is a lag in reporting.

In addition to this unprecedented level of fatalities associated with a consumer product, the CPSC estimates that in 1985 there were 85,900 ATV-related injuries treated in hospital emergency rooms, up from 63,900 in 1984, 26,900 in 1983 and 8,600 in 1982. In precentage increases, these figures mean that the number of incidents of injury treated in emergency rooms in 1985 was 34 percent higher than in 1984, 300 percent higher than in 1983 and 1,000 percent higher than in 1982. The estimated total of ATV-related injuries treated in hospital emergency rooms for the period since 1982 equals 185,300.

Many of these accidents and deaths involve small children and young people. Many involve severe injuries, including a disproportionately large number of spinal cord injuries resulting in victims becoming paraplegics and quadraplegics. A CPSC review of the fatalities reported to date indicate that 46 percent of the victims were under 16 years of age and 22 percent were under 12 years of age. Although the annual estimate of ATV-related injuries appears to be leveling off, the actual numbers continue to be extremely high and the percentage increase over previous years' injuries is still very substantial. Between 1984 and 1985, for example, the percentage increase in estimated emergency room treated ATV-related injuries was 34 percent, compared to an increase of 138 percent between 1983 and 1984, and 213 percent between 1982 and 1983. ATV-related injuries are substantially higher than proportionate figures for minibikes/trail bikes and snowmobiles which are similar off-road recreational vehicles.

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[1] ATV's are motorized, off-road, three- and four-wheeled cycles with balloon-like, soft tires for use in sand, mud, open fields and other terrains. They are intended to be ridden by a single person at one time, having a seat designed to be straddled by the operator and handlebars for steering control. They are used primarily for recreation. A limited number are used on farms, golf courses, and for transportation in places where roads are poor or nonexistent such as rural Alaska. ATV's typically have gasoline-powered engines of between 50 and 250 cubic centimeters displacement. Many ATV's have no rear axle differential and limited suspension systems.

[2] Estimate based on statistics contained in Memorandum to the Commission dated October 10, 1985, from Rae Newman, Subject: "Update of ATV Injuries and Deaths."

In testimony before the Commerce, Consumer, and Monetary Affairs Subcommittee, one of the CPSC Commissioners, commenting on "the alarming *rate of increase* of serious injuries and deaths" connected with ATV use said, "I've not seen anything like it for any product hazard in my nearly six years serving as Commissioner of this agency." [3] Commissioner Saundra Brown Armstrong also referred to the "unprecedented emerging hazard." [4] Another Commissioner, Carol G. Dawson, called the statistics on ATV-related deaths and injuries "grim." [5] Then Chairman Terrence M. Scanlon called the figures "alarming" and "tragic." [6] Congressman Larry Craig called the "recent increase in deaths and injuries related to * * * all-terrain vehicles * * * of great concern" and "alarming." [7] American Honda Motor Company called the rise in the number of accidents "an ominous note." [8]

In early 1984, the Commission began an investigation of ATV-related incidents in light of what was clearly emerging as an exceptionally serious safety problem. Although first introduced in the late 1960's, the ATV began a surge of popularity in the early 1980's. Sales jumped from 136,000 units in 1980 to approximately 650,000 units in 1984. It is estimated that by the end of 1985 there were 2.1 million ATV's in use, and there are, of course, many users for each vehicle sold.[9] There is also a rental market where a person who does not own a vehicle can rent by the hour or the day.

Because ATV's are intended for off-road use, they are not regulated by the Department of Transportation's National Highway Traffic Safety Administration nor subject to its Federal Motor Vehicle Safety Standards. The CPSC is the only Federal agency with jurisdiction to regulate ATV's. In addition, there are few State laws regulating their use and fewer still imposing licensing or training requirements. There are no legal impediments to young children using ATV's. In fact, several manufacturers sell models intended for use by children as young as 6 and 7 years of age.

As a result of these unprecedented factors concerning their use, it quickly became apparent that the ATV presented a unique safety challenge to the Commission. As then CPSC Chairman Terrence Scanlon stated in his testimony before the subcommittee:

> There are other aspects worthy of consideration. Equipped with three soft, balloon-like tires, many ATV's not only remind people of tricycles but they have a stable appearance that makes them seem appropriate for users of all ages and skill levels. However, ATV's possess unique performance and handling characteristics that come into play, for example, when they are maneuvered around

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[3] Hearings before a subcommittee of the Committee on Government Operations, House of Representatives, "Consumer Product Safety Commission's Response to Hazards of All-Terrain Vehicles (ATV's)," 99th Congress, 1st Session, May 21, 1985. Hereinafter referred to as "Hearings." At p. 189, emphasis in original.

[4] Ibid., p. 168.

[5] Ibid., p. 180.

[6] Ibid., p. 151.

[7] Ibid., p. 2.

[8] Ibid., p. 247.

[9] American Honda Motor Co., the manufacturer with the largest share of the ATV market, estimates that seven to eight people would share two to three vehicles during a given weekend. Hearings, p. 248.

turns or up and down hills. These characteristics, coupled with the ability of the vehicle to travel over rough and varied terrain at speeds up to 50 miles per hour, can tax an operator's skill, strength and coordination to the limit—and sometimes beyond.

What all-too-frequently happens is that a sudden shift in direction or change in terrain brings about a change in equilibrium which, in turn, can cause the rider to lose control of the vehicle. Subsequently, the ATV tips over, either forward or backward, or rolls over to either side, and those riding it are thrown off. Of course, proper training would help prevent those kinds of accidents, but such training isn't always available. This year, for instance, the ATV industry hopes to provide training to approximately 42,000 ATV operators, but that is just a small fraction of the total number of people who are likely to drive an ATV at one time or another.[10]

Since early 1984, when the Commission's injury surveillance system first began to track the extent of the ATV death and injury problem, the CPSC has moved in an excessively deliberate fashion to deal with the known hazards. In the committee's view, the CPSC has acted irresponsibly in not utilizing its ample enforcement powers to deal in a meaningful and expeditious manner with the mounting toll of deaths and injuries from ATV use. Instead of using its enforcement powers, it has relied for over 2 years on investigations, on information dissemination and educational measures. Judging by the death and injury rates, these measures have been ineffective in lessening the toll. In fact, the bulk of the hundreds of deaths and the tens of thousands of serious injuries associated with ATV use have occurred since the Commission first became aware of the ATV problem.

The CPSC has also conducted indepth investigations of ATV-accident cases, and has met with industry representatives to monitor the industry's educational and training efforts and to determine if a voluntary standard can be agreed to. In April 1985, the Commission adopted a plan of action to gather more information and announced its intention to commence a rulemaking proceeding by issuing an Advance Notice of Proposed Rulemaking (ANPR). The Commission staff began a hazard analysis to obtain detailed information on ATV use and it began engineering, human factors, medical and economic analyses of ATV's and their use. The Commission also held a series of public hearings throughout the country to disseminate information and to gather additional data.

The actions the Commission and the industry presently have under consideration, including proceeding under an Advance Notice of Proposed Rulemaking, will not have an immediate impact in halting the continuing toll of deaths and injuries related to ATV use. The Commission staff anticipates that the results of its hazard analysis, engineering and other studies will not be completed until the end of fiscal year 1986. Additional months will likely pass before the Commission acts on the basis of these studies. Judging

[10] Ibid., p. 152-153.

by the pace of previous Commission actions, long delays are commonplace before the agency acts on a known hazard. In the case of the hazard arising from methylene chloride, it took the CPSC 18 months to vote for a specific regulatory option from the time its staff received confirmation of the potential hazard. Even after the Commission determines a course of action, it will likely be opposed by the industry in court actions if the Commission uses its enforcement powers. In short, nothing is likely to be done, under the present timetable, to halt ATV-related deaths and injuries within the foreseeable future.

In the meantime, deaths and injuries continue to mount with neither the Commission nor the industry acting in a meaningful way to lessen the hazards associated with ATV use. In the Commission's case, this is not because it lacks the power to do so. As this report makes amply clear, the CPSC has substantial powers to deal with the ATV issue on a firm and expedited basis if it chooses to do so. However, as evidenced by past actions and recent votes and statements, the majority of the sitting CPSC Commissioners do not have a predisposition to use the enforcement powers Congress conferred on the agency to rid the marketplace of an unsafe product such as ATV's. In the industry's case, of course, it has the power to engage in a voluntary recall or to provide specific warnings to previous purchasers of the dangers associated with ATV use. Yet neither the Commission nor the industry has taken action to stem the rising death and injury toll in an immediate and effective manner beyond the issuance of warnings. The Commission has not even informally requested the four major manufacturers—Honda, Kawasaki, Yamaha and Suzuki—to consider a voluntary recall. It has not requested the manufacturers, for example, to cease making a small ATV model intended only for very young children. The manufacturers have done nothing beyond initiating training programs, issuing warning labels and participating in proceedings which may result in a voluntary standard sometime in the future. It should be noted when the Commission first decided to act in April 1985, 104 deaths were known to have been associated with ATV use. Today the toll of fatalities is four times that number.

Under all these circumstances, the committee believes it essential that it interpose its judgment, and to recommend to the Commission, the industry and the Congress the course of action it believes necessary. The committee is firmly convinced that sufficient data has already been disclosed and sufficient analysis performed to justify immediate enforcement action by the CPSC. Interim reports to the Commission by staff working on the ATV matter make it clear that the staff's final report will only substantiate and expand the basic data already known. The most important information—the number of deaths and injuries, the severity of injuries and the age groups of the victims—is updated constantly and is well known. To wait for additional data will only add to the toll; it will not diminish the critical mass already available.

In general, the prerequisite for enforcement action by the Commission are findings that (a) the risks associated with a product's use are "imminent and unreasonable" or (b) that a product's use presents a "substantial risk of injury" to the public. It is the committee's view, based on data already available, that both such find-

ings are required with respect to ATV use—that ATV's present both an imminent and unreasonable risk and that they pose a substantial risk of injury. Given the inevitability of this conclusion, the committee believes it has a duty to set forth its findings and recommendations without awaiting further Commission processes which cannot change the basic conclusion that an unreasonable risk of injury presently exists.

In this context it is useful to compare the ATV death and injury record with that of various other consumer products which have been recalled or banned by various Government agencies and/or which have been voluntarily recalled by the manufacturers. To make this comparison, the committee asked the Congressional Research Service for data on recent consumer product recalls. In response, CRS prepared a "CRS white paper" which is attached to this report as appendix A. The important point to note is that in none of the product recalls or bans did the number of deaths or injuries associated with a particular product even approach the levels associated with the ATV's. As noted, 415 fatalities are known to have occurred in ATV-related accidents since 1982 and 185,300 people are estimated to have been treated in hospital emergency rooms since that time for ATV-related injuries. In the case of the Ford Pinto recall, there were 61 deaths. For the antiflammability chemical, Tris, there were no known deaths or injuries. For the Dalkon Shield, there were approximately 20 deaths. For Rely brand tampons, 25 deaths have been attributed to toxic shock syndrome. For Oraflex, there were 3,000 adverse reaction reports and more than 60 deaths. For Tylenol capsules, there were seven deaths due to cyanide poisoning in 1982 and a fewer number more recently.

In the case of products for which the CPSC has jurisdiction, there have been 3,700 recalls of 327 million units of production. As Chairman Doug Barnard pointed out in the Commerce, Consumer, and Monetary Affairs Subcommittee's hearing, "in none of these recalls has there been the level of documented deaths and injuries associated with the ATV's."[11] In fact, in previous CPSC recall proceedings, far fewer deaths and injuries were documented than are already related to ATV use. In the case of liquid petroleum gas valves, approximately 100 deaths were documented. In the case of asbestos risks from hair dryers, 22 million units involving more than 40 manufacturers were recalled with no known deaths established. Squeeze toys for infants were recalled where four deaths were documented. In early June 1986 the Commission moved to recall 1.6 million crib toys after two babies had strangled on the string used to tie them. The manufacturer of the toys insisted, as do the ATV manufacturers, that the toys are safe when used properly, that a warning to parents should be sufficient and that a recall was unnecessary. Nevertheless, the Commission found a "substantial risk of injury" under the Federal Hazardous Substances Act because children may strangle. Other than the fact that there have been 415 deaths associated with ATV's (as opposed to two for these toys), the committee finds no justification for the

[11] Ibid., p. 202.

Commission's differing regulatory approach to ATV's and to these toys, at least with respect to their use by children.

The statutory basis for Federal agency enforcement action under a variety of safety laws is a fundamental judgment that a product presents an unreasonable, substantial, or an imminent risk of injury. Such a decision, of course, must be supported by available evidence. But in the final analysis, enforcement action is based on the decisionmaker's judgment, weighing all of the factors and balancing benefits against costs. Absent clearly mitigating circumstances, the fact that past CPSC and other agency decisions to use recall authority were exercised on the basis of far fewer deaths and injuries than those associated with ATV use is, by itself, extremely persuasive, especially when the statute only requires a judgmental decision of what is reasonable.

As the CRS report notes, each of the recalls discussed in its report represents a unique situation and comparisons among them or between them and a possible recall of ATV's is difficult to make. Nevertheless, it must be emphasized that in each of these prior cases, a significantly lower death and/or injury toll gave rise to significant and costly voluntary or forced recalls. This data is useful in determining, with respect to the ATV issue, whether the CPSC is acting in a reasonable way to enforce the product safety laws. The committee's conclusion is that it is not

The committee finds, as the report demonstrates, that the CPSC and the industry presently have the power and the data necessary to deal with the ATV-accident problem, but have neglected to do so. Accordingly, the committee strongly recommends that the Commission and the industry take certain steps to remedy this failure. It further recommends that if the CPSC and the industry fail to act responsibly, that Congress step in to require them to act. It should be noted that there are two related problems in controlling the continuing ATV toll—the deaths and injuries resulting from the 2.1 million vehicles on the road; and what to do about future production. Both aspects of the problem must be addressed by the CPSC if the injury and death statistics are to be reduced.

The committee finds that there is sufficient evidence presently in the CPSC record to justify a ban on or suspension of future ATV production and sales; and a recall of ATV's currently in use. Sales should be permitted to resume only after a standard is developed to reduce the unreasonable risk of injury and death associated with their use.

In reaching these conclusions and recommendations, the committee has considered the argument presented repeatedly by the ATV manufacturers that the basic cause of ATV injuries is rider misuse and that the vehicle itself is not at fault. The manufacturers contend that inappropriate rider behavior—use while under the influence of drugs or alcohol, failure to use safety equipment and other dangerous rider practices—are the major causes of accidents and injury. Aside from the fact that children may be unable to understand and accept the risks of ATV use, and that others may be unaware of the risks, no evidence was presented to the committee that would establish a cause and effect relationship between large scale rider misbehavior and negligence, on the one hand, and the mounting toll of deaths and injuries, on the other. The basic fact

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remains that deaths and injuries are unreasonably high for the universe of riders. Moreover, it is the Commission's duty under the law to stop the havoc when the degree of deaths and injuries reaches its present level, regardless of possible rider misuse or neglect.

The manufacturers also contend that appropriate training and experience with the vehicles will reduce injuries. Aside from the fact that there are no requirements for such training and that proportionately very few people are trained, evidence indicates that even experience in riding does not offer any real protection since many of those injured are experienced riders. As the Commission itself has observed:

> The basic configuration of the ATV and its unique performance characteristics, including dynamic stability and handling, appear to play a major role in accidents involving ATVs. Many of the serious injuries and deaths reported in the in-depth investigations resulted from loss of control of the ATV and were observed regardless of whether alcohol, riding double, or speeding were also observed. These incidents involved drivers of all ages. Also, although some victims were first time ATV users, many had previous experience riding ATVs and experience riding motorcycles or minibikes. While drivers of all age groups have been injured or killed in ATV related accidents, a great many fatalities and injuries involve children.[12]

Under these circumstances, it is the duty of the Commission to act under the mandate provided by Congress. If the Commission will not act, it is the responsibility of Congress to require it to do so.

In its examination of the CPSC's response to the hazards of ATV's, the subcommittee's investigation followed several paths. It requested and received all relevant documents from the Commission. Data from the major manufacturers of the vehicles were also received. In addition, a hearing was held on May 21, 1985, at which time testimony was heard from the CPSC Commissioners, the major manufacturers, medical, legal and engineering experts, as well as several persons injured in ATV accidents.

This report compiles the findings of the subcommittee's investigation to date and makes recommendations to the Commission, the industry, the States and the Congress.

II. Background

(1) In the past 4 years, there has been a dramatic increase in the number of deaths and serious injuries associated with ATV use. Since 1982, 415 ATV-associated fatalities are known to have occurred. As of the beginning of this year, there were 26 reported deaths in 1982, 79 in 1983, 136 in 1984 and 174 in 1985. A CPSC staff review of these deaths revealed that 191 of the victims or 46 percent were under 16 years of age and 91 of the victims or 22 percent were under 12 years of age.

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[12] Advance Notice of Proposed Rulemaking, Federal Register, May 31, 1985 (Hereinafter, "ANPR"), p. 23141.

(2) CPSC estimates from its National Electronic Injury Surveillance System (NEISS) that the number of hospital emergency room treated injuries associated with ATV's in 1984 were almost two and one-half times the number in the previous year and more than seven times the number in 1982. Estimated figures for 1985 show a 34-percent increase in injuries over the same period in 1984. Injuries for 1985 are estimated at 85,900, compared to 63,900 in 1984, 26,900 in 1983 and 8,600 in 1982.

(3) A significant portion of the deaths and ATV-related injuries occur to young people. In 1983 and 1984, three-fourths of the victims of ATV-related injuries were between the ages of 5 and 24 years. Almost one-third of ATV injuries involved children under 15 years of age.

(4) In comparing ATV injury and death rates with rates for minibikes/trail bikes and snowmobiles (similar off-road recreational vehicles), the CPSC staff has found that ATV-related injuries are nearly double those for minibikes and trail bikes and more than eight times those for snowmobiles.

(5) A substantially larger number of deaths and injuries are associated with ATV use than with various other consumer products which have been recalled or banned by various Government agencies and/or which have been voluntarily recalled by the manufacturers in recent years.

(6) The CPSC estimates that there were 1.81 to 1.85 million ATV's in use at the end of 1984 and 2.1 million vehicles in use at the end of 1985. Since 1980, shipments of ATV's have increased substantially while other motorized road recreational products such as trail bikes and snowmobiles have declined in sales.

(7) Preliminary CPSC estimates indicate that for 1984 economic losses resulting solely from hospital emergency room-treated ATV-related injuries may approach $100 million, excluding pain and suffering. No economic loss estimates exist for the 136 deaths known to have occurred in connection with ATV use in 1984.

(8) The CPSC is the only Federal Government agency with jurisdiction for ATV safety. Although several States have laws dealing with some aspects of ATV use, no State law deals with the safety issue in a comprehensive manner.

(9) In early 1984, as a result of the data collected by CPSC on the increasing numbers of deaths and injuries, the Commission began an investigation of ATV-related incidents. CPSC staff began to conduct indepth accident investigations and began to collect economic, epidemiological, engineering, human factors and medical data on ATV injuries. In December 1984 and March 1985, the Commission and the Specialty Vehicle Institute of America (SVIA), a trade association representing manufacturers and distributors of ATV's, jointly issued safety alerts warning consumers of the potential risks associated with ATV's.

(10) CPSC staff investigations indicate that the basic configuration of an ATV and its unusual performance and handling characteristics, including dynamic stability and handling, appear to play a significant role in ATV-related accidents. Although "human error" factors such as inebriation, riding with passengers, operating the vehicle on hard surface roads, and violating the rules of the road may contribute to some accidents, no evidence exists to justify

the assertion that widespread driver misconduct is a significant factor in the large number of deaths and injuries resulting from ATV use. Absent such evidence, it is difficult to escape the conclusion that the dynamic stability and handling characteristics of the ATV are the most prominent factors causing a loss of vehicle control. Loss of control following an abrupt change in equilibrium such as a sudden change in terrain or direction is a common form of ATV accident. This change in equilibrium and subsequent loss of control often results in a pattern in which the machine overturns or the rider is thrown off.

(11) The ATV is a "terrain-active" or "rider-interactive" vehicle, which means that the driver must respond to uneven and changing terrain by a shift in weight, manipulation of hand and foot controls and steering. Accidents occur as a result of a wheel striking an object or encountering a sudden change in terrain which may not have been perceived by the driver in time to be avoided and which may cause an ATV response which exceeds the driver's ability to control. The speed of the ATV is sometimes a factor which may contribute to the driver's failure to perceive and accurately respond to environmental conditions, but CPSC staff studies show that 53 percent of investigated accidents occurred at speeds estimated to be under 16 miles per hour. CPSC staff studies demonstrate overturning and loss of control in a majority of investigations, regardless of possible rider misuse and regardless of the experience of the user. There is some evidence that the manipulative skills necessary to operate an ATV safely are extremely complex and not easily acquired by the average rider. Concern has also been expressed as to whether young children have the physical skills, strength and good sense of judgment necessary to operate ATV's without undue hazard of injury. Some observers maintain that in order to ride a three-wheeled ATV correctly, one must cause the ATV to become unstable.

(12) In spite of industry efforts to stress safety through education, there are still instances of purchasers and riders being unaware of the risks of ATV use and examples of advertisements which have the effect of encouraging unsafe riding practices.

(13) Based on available data, the Commission has preliminarily determined that there may be an unreasonable risk of injury associated with the use of ATV's which may be sufficiently severe to require regulatory action by the Commission.

(14) The CPSC has ample statutory compliance and enforcement powers to deal in a timely and effective manner with the risks associated with ATV's. These powers include the following:

(a) *Rulemaking:* Under section 7 of the CPSA, the Commission is authorized to promulgate a mandatory safety standard setting forth certain performance requirements for the product, or requiring that a product be marked or accompanied by clear and adequate warnings or instructions.

(b) *Banning:* Under section 8 of the CPSA, the Commission is authorized to promulgate a rule declaring a product to be a banned hazardous product where the product presents an unreasonable risk of injury and no feasible safety standard would protect the public from the risk.

(c) *Hazardous Substance:* Under the Federal Hazardous Substances Act (FHSA), administered by the Commission, if it is determined that some or all ATV's are articles intended for use by children, the Commission may promulgate a rule declaring all ATV's or certain ATV's which do not meet specified requirements, to be hazardous substances because, during normal use or when subjected to reasonably foreseeable damages or abuse, they present a mechanical hazard as defined in the FHSA. An article intended for use by children which has been declared by rule to be a hazardous substance is banned under the FHSA.

(d) *Imminent Hazard Action:* Section 12 of the CPSA authorizes the Commission to file an action against an imminently hazardous consumer product, against any manufacturer, distributor or retailer of an imminently hazardous consumer product or against both if the product is one that presents an imminent and unreasonable risk of death, serious illness or severe personal injury. The court is empowered to grant such relief as may be necessary to protect the public from the risk, including notice to purchasers of the product, public notice, or recall, repair or replacement of the product, or refund of the purchase price. Under the FHSA, if a children's article is found to present an imminent hazard to the public health because of a mechanical hazard, the article is deemed to be a banned hazardous substance and its introduction into interstate commerce is prohibited until a rulemaking proceeding is completed.

(e) *Public Notice and Repair, Replacement or Refund of Purchase Price:* Under section 15 of the CPSA, if the Commission determines that ATV's contain a product defect which, because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk or otherwise, presents a substantial risk of injury to the public ("substantial product hazard"), the Commission may order manufacturers, distributors or retailers to take appropriate action to adequately protect the public. This action may include giving public notice of the defect, mailing notice to any person known to have received the product, and ordering repair, replacement or refund of the purchase price of the product at the manufacturer's, distributor's, or retailer's election.

(f) *Performance and Technical Data:* The Commission has ample authority under the CPSA to compel needed data (including oral testimony and specific documents) by means of a special or general orders and/or subpoenas. Further, section 27(e) of the CPSA provides that the Commission may require, by rule, that manufacturers of ATV's provide to the agency performance and technical data related to the performance and safety of ATV's. The Commission could also require that each manufacturer provide such performance and technical data directly to original purchasers of ATV's (distributors or retailers) and to consumers.

(15) On April 3, 1985, the Commission voted to commence a rulemaking proceeding by issuing an Advance Notice of Proposed Rulemaking (ANPR) under the authority of sections 9(a) of the CPSA and 3(f) of the Federal Hazardous Substances Act. The Commission solicited comments and information on a variety of issues relating to ATV use and possible safety regulation. In response to the ANPR, comments and submissions were requested by the Commission by July 30, 1985, and extended to September 30, 1985. As of

the date of this report, neither the Commission nor SVIA has proposed a voluntary standard for dealing with the risk of injuries associated with ATV's, nor is there an existing voluntary standard which would eliminate or adequately reduce the risk of injury associated with ATV use.

(16) On April 3, 1985, in addition to announcing its intention to commence a rulemaking proceeding by issuing an Advance Notice of Proposed Rulemaking, the CPSC staff was ordered to embark on the following steps:

(a) Conduct a hazard analysis to obtain detailed information on ATV use.

(b) Undertake an engineering, human factors and medical analysis of ATV's and their use.

(c) Hold a series of public hearings in five locations around the United States to solicit user and consumer input. In total, six hearings have been held, with one in California in October 1985, and the last in Alaska in March 1986.

(d) Monitor the development of voluntary standards of ATV's, pending review of future data and industry activity.

(e) Share information with user groups and State, local and Federal officials.

(f) Monitor the ATV industry's education and training effort, reserving the right to assist or strengthen the industry effort.

The Commission allocated for the ATV project, including staff time, $994,000 for fiscal year 1985; $1.1 million in fiscal year 1986; and $864,500 for fiscal year 1987. These funds and staff resources have been reprogrammed from other CPSC projects and do not represent additional appropriations.

(17) The Specialty Vehicle Institute of America (SVIA) has indicated a willingness to begin developing a voluntary standard and has informed the Commission staff that it has initiated steps to develop such a standard using the procedures of the American National Standards Institute (ANSI). The Commission staff has informed SVIA that any voluntary standard on ATV's should include provisions for minimum age recommendations, training and ATV performance characteristics, such as dynamic stability. As of the date of this report, no voluntary standard has been promulgated.

(18) SVIA has also developed an ATV rider training course aimed at promoting safe and responsible use of ATV's. The course covers protective gear, controls, preride inspection, local laws, safe riding practices, strategies for riding on a variety of different terrains, starting and stopping the engine, principles of turning, climbing and descending hills, emergency maneuvers, and riding over obstacles. There are no requirements that such training courses be given before a vehicle is sold or used. During the first year, it was estimated SVIA's rider training program would reach a small fraction of riders, or about 42,000 riders out of an estimated 2.1 million units in use. In fact, only some 5,000 riders were trained in 1985.

(19) Some manufacturers are beginning to label their products with warnings of the potential hazards in ATV use and are urging minimum age limits to operate an ATV. There is no agreement among manufacturers on what the minimun age should be. More-

over, certain smaller models are manufactured by some producers expressly for children.

(20) ATV's are manufactured and sold primarily by four Japanese manufacturers—Honda, Kawasaki, Yamaha and Suzuki, with Honda the primary force in the market. ATV manufacturers allege that inappropriate rider behavior is the major cause of accidents and injury, that it is misuse of the vehicle rather than the vehicle itself that is at fault. Accordingly, manufacturers have stressed driver training, labeling and other safety information and educational techniques in dealing with the hazards of ATV use.

III. Findings

(1) The committee finds that the use of ATV's presents both an unreasonable and an imminent risk of death and serious injury requiring immediate enforcement action by the Consumer Product Safety Commission. An adequate data base has long since existed for making this determination.

(2) The committee finds that the Congress has provided the CPSC with ample emergency authority to eliminate from the marketplace on an expedited basis, unreasonably hazardous consumer products. By failing to use these special powers to prevent continuing deaths and injuries related to ATV use, the CPSC has failed in its responsibility to protect the public.

(3) The committee finds that ATV's present an imminent and unreasonable risk of death, serious illness or severe personal injury under section 12 of the Consumer Product Safety Act.

(a) The committee's finding of an "unreasonable" risk is based on a balancing of the likelihood and severity of the injuries that may result from ATV use against the harm such a finding imposes upon manufacturers and consumers. This balancing includes consideration of the following:

(i) Number and severity of injuries and deaths: Injuries and deaths associated with ATV use are unacceptably high. Injuries and deaths attributable to ATV use already exceed the toll attributable to any product known to have been banned or recalled through Federal regulatory agency action.

(ii) Distribution of injuries by age groups: A significant number of ATV injuries occur among children who are unable to adequately protect themselves from the hazard.

(iii) Analysis of number of deaths and injuries and severity of injuries as compared to similar products: ATV-related injuries and deaths, in absolute and relative terms, exceed those attributable to similar products such as motorcycles or snowmobiles.

(iv) Information concerning the utility of the product: ATV's are used primarily for recreational purposes.

(v) Engineering and technical data: Because of their stable appearance, many users are deceived into believing that ATV's may be driven safely by users of all ages and skill levels. In fact, the vehicle's unique handling characteristics require substantial skill, strength and coordination to operate safely.

(vi) Human factors: Even experienced riders who have not engaged in rider misuse are often the victims of fatalities and serious injuries.

(vii) State laws: State laws are inadequate to deal with the problem.

(viii) Voluntary action: Voluntary training programs and voluntary standard development by manufacturers of ATV's have been exceedingly slow and inadequate to deal with the risks of ATV use.

(b) The committee's finding of an "imminent" risk is based on a review of numerous accident reports and other data demonstrating that loss of control of the vehicle leading to death or serious injury can manifest itself virtually at any time and occurs regularly regardless of whether rider misuse is involved or not. It is also based on the absence of any demonstrated correlation between significant driver misuse and injury from vehicle use.

(4) The committee finds that ATV's constitute a substantial product hazard under section 15 of the CPSA. This finding is based on the large and increasing number of ATV incidents involving serious injuries and deaths; the large and increasing number of products in use; the fact that all of the products present the potential for serious injury or death; the fact that overturning and loss of control are found in a majority of investigations regardless of possible rider misuse and regardless of the experience of the rider; and the inability or unwillingness of users to understand or heed warnings and instructions accompanying the product in many cases.

(a) The committee finds that ATV's present one or more of the following types of patterns of defects (any one, combination, or all of which could present a substantial product hazard): A design defect based on inherent instability; a defect based on failure to adequately warn the rider of the hazards and risk of injury presented by the vehicles; a defect based on failure to adequately instruct the rider in the use, operation and maintenance of the vehicles; and defects relating to specific components of the vehicles.

(b) In determining whether the risk of injury presented by ATV's is the type of risk which render these vehicles defective, the committee finds as follows: ATV's are used primarily for recreational use; therefore, the utility and benefits afforded to the general public by their use are limited. In contrast with the limited benefits, the nature of the risk of injury is severe, including paralysis and death. The risk of injury is substantial in both absolute and comparative terms, and is increasing at an alarming rate as the estimated number and use of ATV's increase. The populations at risk are primarily children and young adults. Children may not have sufficient motor skills or ability to understand or appreciate the hazards and risk of injury presented by the ATV's. Young adults may not be likely to appreciate these concerns either. It is also questionable whether the user population in general would follow warnings relating to these concerns, or instructions for use of the vehicles.

(5) The committee finds that the steps already taken by the CPSC, the ATV-manufacturers and the States to deal with the ATV-safety problems have not yet and will not soon result in

timely remedial actions to prevent continued deaths and injuries related to ATV use.

IV. Recommendations [13]

I. The committee recommends to:

A. THE CONSUMER PRODUCT SAFETY COMMISSION

(1) At a minimum, the CPSC should act immediately under section 3(e)(2) of the Federal Hazardous Substances Act (FHSA) with respect to ATV's intended for use by children, to promulgate a rule declaring all such ATV's to present an imminent hazard to the public health and thus declared to be banned hazardous substances.

(2) The committee believes, however, and thus recommends that a more acceptable and comprehensive public policy approach is to recall all three-wheeled vehicles. Accordingly, the CPSC should immediately take action under section 12 or 15 of the Consumer Product Safety Act (CPSA) to seek a recall of all ATV's, with costs to be borne by the manufacturers of such vehicles, and to seek such other remedies as provided for in those sections.

(3) With respect to future production of ATV's and in order to insure the safety of ATV's sold hereafter, the CPSC should establish a deadline of August 1, 1986, to issue a proposed safety rule to deal with the hazards associated with ATV use. If the Commission finds that no feasible safety standard would adequately protect the public, it should promulgate a rule under section 8 of the CPSA declaring ATV's to be a banned hazardous product.

II. In the event the CPSC fails to act immediately, the committee recommends to:

B. MANUFACTURERS OF ATV'S

(4) Manufacturers should immediately halt current production and sale of ATV's.

(5) Manufacturers should immediately contact every existing ATV owner to apprise them of the rising accident and fatality rate and the risks of ATV use, especially to children; and should inform ATV owners of explicit safety precautions to be undertaken. In addition, manufacturers should make training courses available to all current owners of ATV's.

(6) Manufacturers should immediately develop a voluntary standard to eliminate or adequately reduce the risk of injury associated with ATV's. Such a standard should incorporate the age and training recommendations set forth in paragraph 11 below. It should also deal with ATV performance characteristics such as dynamic stability and handling.

(7) Manufacturers should include safety equipment (such as a protective helmet) in the price of ATV's unless proof of ownership of a helmet is presented.

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[13] Recommendations deal solely with three-wheel ATV's.

(8) Manufacturers should stress the need for safe riding practices in their ATV advertisements. They should eliminate advertisements showing dangerous practices.

(9) In order to eliminate ATV use by children, manufacturers should permanently cease producing small-sized vehicles for use by children.

(10) Manufacturers should utilize rotating warning labels (akin to the schedule currently utilized for health warnings in cigarette advertising) on all ATV advertising material in print, audio or telecast media. Such warnings should also be included in all ATV owner manuals. These warnings should deal with use by children under age 14; the danger of tipping over upon encountering obstacles, slopes, or during turns; the fact that ATV's require special riding skills; it should warn against use by more than one person; and should advise that riders should complete training courses before riding and should always wear a helmet, boots, gloves, and other protective gear.

C. STATES AND LOCAL GOVERNMENTS

(11) All States should adopt comprehensive laws governing the regulation and use of ATV's. These laws should require:

(a) Use of ATV's should be prohibited by children under the age of 12 years.

(b) All persons under 16 years of age should be required to attend and pass a training course in the safe use of ATV's before they are licensed to use such vehicles.

(c) All persons using ATV's should be required to wear protective head gear. States should mandate that helmets are required to be sold along with a new vehicle, unless proof of ownership of a helmet is presented. Similarly, helmets should be included in all rentals of ATV's.

(d) States should require such other safety equipment, such as lights, flags or speedometers, as may be necessary under the circumstances of use in the particular State.

(e) States should prohibit the use of ATV's if the driver is under the influence of alcohol or drugs.

(f) States should restrict the operation of ATV's on public streets and highways.

D. CONGRESS

(12) Unless the CPSC, the manufacturers and the States comply with the recommendations set forth above in paragraphs 1–11, Congress should act to require compliance.

V. Discussion

A. SCOPE OF THE PROBLEM

(1) Deaths and injuries

The most significant fact in reaching the committee's conclusion that the CPSC should utilize is enforcement powers against ATV's without further delay is the unprecedented level of deaths and injuries associated with ATV use and the rapid increase in the rate

of these casualties since the problem first became known to the CPSC. The most recent figures compiled by the CPSC show an unacceptably high level of deaths and injuries.[14] By January 31, 1986, the Commission had reports of 415 ATV-related deaths which occurred between 1982 and 1985 with the death toll increasing dramatically each year. By one estimate, four to five poeple will die every week this spring and summer if the death rate for these months continues at last year's pace. A review of the 415 known fatalities indicated that 191 victims were under 16 years of age (46 percent) and 91 victims were under 12 years of age (22 percent). In 1985 alone, the CPSC had reports of 174 dealths, with more to be counted since there is a lag time in reporting to the Commission.

In addition to this unprecedented level of fatalities associated with a consumer product, the estimated total of ATV-related injuries treated in hospital emergency rooms for the period since 1982 equals 185,300. In 1985, there were 85,900, up from 63,900 in 1984, 26,900 in 1983 and 8,600 in 1982. In percentage increases, these figures mean that the number of incidents of injury treated in emergency rooms in 1985 was 34 percent higher than in 1984, 300 percent higher than in 1983 and 1,000 percent higher than in 1982.

The problem of ATV-related deaths and injuries has increased markedly in a relatively short time since it was first recognized in early 1984. At that time, CPSC's Epidemiology Directorate noted a large increase in injuries with ATV's as reported through the agency's National Electronic Injury Surveillance System (NEISS).[15] The number of estimated injuries had increased eight-fold, from about 8,000 in 1982 to over 60,000 in 1984. During the same period, ATV shipments had increased from 306,000 in 1982 to 650,000 in 1984.[16]

Prior to the December 1985 report, the Commissioners were briefed concerning its staff's ongoing investigation in June and July 1984. The July 1984 report stated that the "estimated frequency of hospital emergency room treated injuries associated with three-wheeled ATV's has increased dramatically over the past 5 years from 2,948 in 1979 to 27,554 in 1983." [17] It also characterized the hospitalization rate for ATV's for 1982–1983 as "twice the rate for minibikes and trail bikes, and considerably greater than the rate for snowmobiles." [18] The report continued:

> * * * Twice as many fatalities were reported through the death certificate project for ATV's as for mini-bikes/trail-bikes during the 1982–1983 period. Snowmobile-related fatalities, however, were almost three times as frequent as were fatalities involving ATV's.[19]

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[14] Memorandum dated March 4, 1986, from Rae Newman to the Commission, Subject: "Update of ATV Deaths and Injuries."

[15] NEISS collects data on treatment of injured persons from a statistically selected group of hospital emergency rooms. These data are the basis for national projections of injuries which provides the Commission with reliable information on which to base decisions for action that may be needed to protect consumers.

[16] CPSC Survey of All-Terrain Vehicle-Related Injuries (Preliminary Report), December 1985; page 1 (Hereinafter "Preliminary Report").

[17] Memorandum dated July 9, 1984, from Nick Marchica to the Commission, Subject: "All-Terrain Vehicles (ATVs)," p. 1.

[18] Ibid.

[19] Ibid. Honda, the major ATV manufacturer, has objected to these comparisons as follows: "A concern we have with the comparisons that CPSC has made between ATVs and other off-road

Continued

Economic data provided in this and other staff reports demonstrate a dramatic surge in ATV sales, beginning in 1980. While current ATV designs were introduced into the U.S. market in the early 1970's, 1980 was the first year when sales exceeded 100,000 units as follows:[20]

Year	*Sales*
1980	136,000
1981	197,000
1982	306,000
1983	484,000
1984	650,000

Taken together, unit sales for 1982 and 1983 accounted for over 56 percent of all ATV sales up to that date. CPSC staff estimated that over 1.24–1.27 million ATV's were in use by the end of 1983. It is estimated that the number of ATV's in use by the end of 1985 was about 2.5 million.[21]

By the time the Commission voted to issue an Advance Notice of Proposed Rulemaking (ANPR) on April 3, 1985, available injury, death, and sales statistics involving ATV's had drastically altered. Total sales had risen to a projected 780,000 units for 1985.[22] While the number of ATV sales increased sharply in 1984, the percentage growth slowed somewhat to 24 percent. Industry estimates put the 1985 rate of growth of the ATV market at 20 percent.[23] Citing this escalation in sales, the ANPR concludes: "[t]he increased use of ATV's has been accompanied by a sharp rise in fatalities and injuries."[24]

The ANPR includes national estimates of injuries each year associated with ATV use and treated in a hospital emergency room. These injuries grew from 8,585 in 1982 to 27,554 in 1983 to 66,956 in 1984. This 1984 tally is almost two and one-half times the number of injuries in the previous year and more than seven times the number of injuries in 1982. For the first 4 months of 1985, there were an estimated 28,000 ATV-related injuries treated in hospital emergency rooms. This figure is approximately 80 percent higher than the estimated injuries treated during the same time period in 1984.[25]

The death toll associated with ATV use is also detailed in the Commission's ANPR. These fatality reports came from a number of sources, including death certificates, medical examiners and coroners, and newspaper clippings. The ANPR notes that although reporting of death certificates by the States was not yet complete for

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vehicles such as snowmobiles and off-road motorcycles is that the latter two categories of vehicles do not have either the year-round usage of an ATV or the higher number of users and user hours per machine that our figures show are typical for ATVs. These considerations suggest that the CPSC data is preliminary in nature and not a proper data base for the drawing of conclusions. Further, off-road motorcycles and snowmobiles are representative of mature and stable markets that have been engaged in safety training and ride familiarization for several years, but ATVs are now peaking in popularity." (Hearings, p. 251)

[20] It should be noted that while sales of ATV's have increased dramatically, there is some evidence that this rapid growth is slowing. Another notable development is the growth in shipments of four-wheel units. In 1984, for example, of the total shipments of 650,000 units approximately 180,000 were four-wheel ATV's. See Memorandum to the Commission dated December 19, 1985, Subject: "ATV Market Sketch."

[21] Hearings, p. 190. The current estimate is that 2.1 million ATV's are now in use.

[22] ANPR, p. 23140.

[23] Ibid.

[24] Ibid.

[25] Ibid.

1983, 1984, and 1985, the Commission had reports of 161 ATV-related fatalities which occurred between January 1982 and April 1985. Of these deaths, 73 of the victims were under 16 years old and 39 were under 12 years of age.[26] As noted earlier, by March 1986, a total of 415 fatalities were known to the Commission. Of this total number, a significant portion of the deaths occurred after the Commission became aware of the problem. A significant number occurred even after the CPSC decided, in April 1985, to make ATV's a priority project. The CPSC was aware of 104 deaths related to ATV's in April 1985; by October 1985, CPSC had reports of 324 deaths, with 125 occurring in the first 9 months of 1985.[27] In short, deaths have mounted while the CPSC has done nothing more than collecting data, issuing warnings and engaging in studies of the problem.

The age distribution of ATV injuries remained approximately the same from 1983 to 1984. Three-fourths (73.6 percent) of the victims of ATV-related injuries were between 5–24 years old.[28] Almost one-third of ATV injuries (32 percent in 1984) involved children under 15 years of age.

The ANPR also compares the overall number of injuries and the number of ATV's in use during 1983 and 1984: [29]

	Estimated hospital emergency room treated injuries per 1,000 ATV's in use	Estimated hospital emergency room treated injuries hospitalized per 1,000 ATV's in use
1983	21.7–22.2	2.58–2.64
1984	38.2–37.0	4.25–4.99

Updating previous Commission information, the ANPR states that the rate of injuries associated with ATV's were nearly double those for minibikes and trail bikes and more than eight times those for snowmobiles. The hospitalization rate for ATV's is described as more than twice that of minibikes and trail bikes. Injuries associated with these other types of vehicles for off-road use have remained about the same from 1983 to 1984, while ATV injuries increased. The ANPR includes the following comparison table.[30]

	Estimated hospital emergency room treated injuries 1984	Percent of cases 1984	Estimated No. in use at the end of 1984 (4.36) million	Estimated hospital emergency room treated injuries per 1,000 vehicles in use	Estimated hospital emergency room treated injuries hospitalized per 1,000 vehicles in use
ATV's	66,958	13.5	1.81–1.85	36.2–37.0	4.88–4.99
Minibikes/trail bikes	33,638	5.1	1.5	22.4	1.14
Snowmobiles	8,078	10.4	1.0–1.5	5.4–8.1	.56–.84

[26] Ibid.
[27] Preliminary Report, p. 1.
[28] ANPR, p. 23141.
[29] Ibid.
[30] Ibid.

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The inevitable conclusion to be drawn from this recitation of deaths and injuries associated with ATV use is that the toll is unreasonably high. The absolute numbers of deaths and injuries are high when compared to the number of units in use and when compared to the rate of injury from other consumer products. Moreover, and perhaps most important, the deaths and injuries impact most severely on the very young who are unable to understand the risks involved, or youths who are unwilling to abide by safety restrictions. Finally, the nature of injuries suffered are unusually severe, with a high proportion of spinal cord injuries resulting in life-time disability in many cases. These factors must be weighed, in making a determination of reasonableness, against the ordinary uses of the product and the costs of eliminating the hazards, among other things. Unlike other consumer products, such as pharmaceuticals and automobiles, ATV's are used largely for recreation and sport, and have limited utilitarian uses. On the other hand, the number of deaths and injuries now known from ATV use already exceeds the toll for many other consumer products which have recently been recalled either voluntarily or by Government process. As indicated earlier, the Congressional Research Service supplied the committee with data on recalls of other consumer products together with the death and injury figures associated with these products' use. In no case does the toll even approach that involved with ATV use. Moreover, the costs to the manufacturers of recalling these products were, in many cases, quite extensive. In the case of the Ford Pinto, it is estimated to be $10 million; Tris, between $40 and $150 million; Dalkon Shield, 9,000 cases already settled for $378 million, plus legal expenses of $107 million, with additional cases pending; Rely tampons, $75 million; Tylenol, in excess of hundreds of millions of dollars. In addition, none of these situations present the skewed impact on children and young adults which is shown in the ATV case.

(2) Indepth investigations

The committee's finding that the CPSC should use its enforcement powers to find that ATV's constitute a substantial product hazard is also based on the indepth investigations of ATV-related injuries and fatalities conducted by the Commission. CPSC staff has conducted two significant indepth studies of ATV-related injuries. In one, 169 accidents were examined; in the other, 295 ATV-related injury cases were evaluated, for a total of 464 indepth studies. The results of both these studies are startlingly similar. Their main findings constitute sufficient evidence for the Commission to act now to utilize its enforcement powers to cease the continued toll of deaths and injuries. Any additional study will only expand on what is already known.

The CPSC staff studies demonstrate that overturning and loss of control are reported in the majority of ATV accidents. These factors are present regardless of whether alcohol, riding double or speeding were also involved in the accident under review. These investigations also indicate that the basic configuration of the three-wheeled ATV, with its solid rear axle and uncommon performance and handling characteristics, appears to play a significant role in these accidents. These studies reveal that many of the incidents in-

volve: (1) sudden loss of control, resulting in the vehicle turning over or colliding with another object; (2) the vehicle overturning (tipover forwards, flipover backwards, or rollover to the side); and (3) the rider unexpectedly falling or being thrown from the ATV.[31]

Many accidents result from an abrupt change in the equilibrium of the vehicle, even at low speeds. CPSC staff's preliminary analysis found that 53 percent of the accidents studied occurred at speeds under 16 mph. A number of factors contribute to these incidents, such as encountering obstructions or sudden changes in terrain. Fully 68 percent of the ATV's CPSC staff studied hit a terrain irregularity or larger obstacle during the sequence of events leading to the injury. Also, unexpected changes in an ATV's equilibrium can occur when the vehicle accelerates, brakes, turns, or swerves to avoid an obstacle. Nearly 28 percent of the ATV accidents reviewed in the preliminary hazard assessment occurred when the vehicle was turning. This same study suggests that even experience in riding may not offer any real protection, since 54 percent of the drivers had at least 1 year's experience driving an ATV at the time of their accident.[32]

Loss of control of an ATV is often followed by a pattern in which the machine overturns, or the rider is thrown from the ATV. The ANPR states that the basic configuration of the ATV and its unique performance characteristics, including dynamic stability and handling, appear to play a major role in ATV accidents. The CPSC also notes that other factors such as use of alcohol, riding with passengers, or operating a vehicle illegally on a public road may obscure the pattern of loss of controls as the critical element in the accident. Nevertheless, CPSC staff believe that the "performance characteristics" of ATV's are the "single most prominent factor identifiable as a cause of loss of control" of the vehicle.[33] The committee believes that apart from any possible misuse or abuse, there is ample evidence for the CPSC to find that the very design of the vehicle renders them inherently unsafe and unreasonably dangerous.

The committee puts great emphasis in its finding of a product hazard on the fact that the CPSC staff studies demonstrate overturning and loss of control in a majority of investigations, regardless of possible rider misuse and regardless of the experience of the user. The manufacturers allege, as Honda observed after analyzing the indepth studies, that "inappropriate rider behavior continues to be a major cause of accidents and injury . . . it is misuse of the vehicle, rather than the vehicle itself that is at fault.[34] However, no evidence for this assertion has been made available by the manufacturers.

The committee also considered the CPSC's most recent data impacting on its finding that ATV's consitute a product hazard. The December 1985 Commission survey of all-terrain vehicle-related injuries discusses the responses to telephone interviews conducted by CPSC staff. Three hundred forty-six (346) injured persons treated in

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[31] Memorandum dated February 11, 1985, from George Rutherford and Jean Kennedy to Nick Marchica, Subject: "Updated Injury Data on All-Terrain Vehicles."
[32] Preliminary Report, pp. 8-9, 12-13.
[33] ANPR, p. 23141.
[34] Hearings, p. 252.

NEISS hospital emergency rooms between May 1 and July 15, 1985, were reported as having ATV-related injuries. Interviewers contacted the households of the injured persons and obtained information to complete 92 percent of the extensive telephone questionnaires.[35] These interviews confirmed that 93 percent of the injuries reported in NEISS were ATV-related. Accordingly, the information from these 295 ATV-related injury cases were evaluated. Weighted estimates from these reports described an estimated 27,100 ATV-related injuries treated in hospital emergency rooms nationwide during the 2½ month study period. Of these cases, 97 percent involved ATV's motion (instead of accidents involving repairs, starting, mounting or dismounting a recently stopped ATV).[36] Only the injuries involving moving ATV's were used for the staff's review of ATV-related injuries and accidents, thus decreasing the weighted estimate to 26,400 persons treated for ATV-related injuries.

Of the estimated 26,400 persons, three-fourths were male. Almost one-half were under 16 years of age; one-fifth were under 12 years of age.[37] Significantly, this report states:

> A hospitalization rate of 18 percent and the report of one passenger dead on arrival at the hospital were indications of the severity of the injuries. The hospitalization rate was over four times the average hospitalization for all products reports in NEISS (4 percent in 1984). Product related deaths were rarely reported at emergency rooms; about one in 2,000 reports during 1984.
>
> About 40 percent of the injuries involved the head, the trunk or over 25 percent of the body; these included fractures, lacerations, contusions and concussions. Over 25 percent of the persons diagnosed with these injuries were hospitalized. The extremities were injured in almost 60 percent of the cases, leg or foot twice as frequently as arm or hand; these injuries included fractures, contusions and strains/sprains. Further analysis is necessary to classify the injuries by temporary or permanently disabling effects.[38]

Thus, the December 1985 study continues to document the facts that exceptionally young people are victims of ATV accidents—over half under 16 years of age—and that injuries are serious. The fact that the hospitalization rate was over four times the average rate for all products reported demonstrates the serious nature of the injuries compared to those suffered by victims of the 900 other products included in the NEISS survey. In addition, the nature of injuries suffered are not trival. These findings weigh heavily in the committee's determination that ATV's constitute a substantial product hazard.

The report further explained that although ATV's are not intended to carry passengers, 20 percent of the injured persons were passengers. Passengers were carried in 31 percent of the estimated

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[35] Preliminary Report, p. 2.
[36] Ibid., p. 5.
[37] Ibid., p. 8.
[38] Ibid.

25,500 accidents which occurred nationwide during the study period.[39] Passengers were younger and included more females than the drivers.[40] While over one-half of all injured persons did not wear protective equipment (such as helmets, gloves, or boots), almost three-fourths of the passengers injured wore no protective gear. The reported death was a passenger. These findings and others demonstrate that warnings are not likely to be heeded by the users of ATV's. In fact, 87 percent of the respondents were aware of a warning label, but 22 percent could not describe what the label said.[41]

Of the estimated 25,500 accidents, over 90 percent occurred during recreational use and a majority occurred in daylight hours.[42] The speed of the vehicle in an accident was estimated, since ATV's usually do not have a speedometer. Over half of the accidents occurred at speeds estimated under 16 miles per hour; less than 20 percent of the speeds were estimated as over 35 miles per hour.[43]

Collisions were the primary event for 35 percent of the accidents. After the collision, three-fifths of these ATV's overturned or tipped. The report notes that "stability may have been a factor in almost half the accidents classified as ATV Overturned (41 percent) or Tipped (7 percent)."[44] In 6 percent of the accidents, the injured person fell, jumped or was thrown from the ATV. The remaining 11 percent of the accidents in this study involved contact of the injured person with the ATV or surroundings (such as when a user or passenger's foot hit the ground or when a user/passenger's hand hit a fence).

The preliminary review notes other important findings:

68 percent of the ATV's hit a terrain irregularity or larger obstacle during the sequence of events leading to the inquiry;[45]

26 percent of the ATV's landed on the injured person;[46]

28 percent of the accidents occurred during turning;

87 percent of the ATV's had three wheels and 13 percent had four wheels;[47]

43 percent of the AVT's had no mechanical suspension, 17 percent had front suspension, and 40 percent had front/rear mechanical suspension,[48]

8 percent of the ATV's had malfunctions involving brakes, throttle, steering, wheels or tires;[49] and

19 percent of the injured persons were under 12 years old while 46 percent under 16 years of old; and 54 percent of the drivers had at least 1 year's experience; 26 percent had less than 1 month's experience.[50]

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[39] Ibid., p. 12.
[40] Ibid., p. 8.
[41] Ibid., p. 24.
[42] Ibid., p. 12.
[43] Ibid.
[44] Ibid.
[45] Ibid., p. 13.
[46] Ibid. In the case of deaths, 61 of the 415 death reports note that the vehicle landed on the victim. See memo to Commissioners from Rae Newman dated March 4, 1986, Subject, "Update of ATV Deaths and Injuries."
[47] Ibid., p. 25.
[48] Ibid., p. 26.
[49] Ibid., p. 8.
[50] Ibid., pp. 8–9.

Another key result of the survey showed that 35 percent of the accidents involved practices that the ATV manufacturers warned against, notably, carrying passengers and driving on paved roads.[51] However, the characteristics of this group were similar to the remaining accidents with respect to frequent collisions, overturning, hitting objects, turning and driving at speeds estimated as low.[52] This finding supports the staff's earlier view expressed in the agency ANPR that notwithstanding inappropriate rider behavior the performance characteristics of ATV's are the single most prominent factor identifiable as a cause of loss of control.

CPSC staff confirm this view by noting in its analysis that additional statistical, engineering, human factors and medical evaluation are needed "to assess the dynamic stability of the vehicle, a factor suggested by the high proportion of overturned ATV's."[53] Finally, the CPSC analysis states that this data "tend to confirm the need for driver education relating to the appropriate use and handling of the all-terrain vehicle and to the importance of protective equipment."[54]

It should be noted that American Honda has objected to the public dissemination of ATV-related injury and death estimates, but the Commission has not seen fit to do so. The committee agrees that the CPSC's estimates are useful in defining the magnitude of a product-related safety problem. In a letter dated September 9, 1985, from American Honda's counsel, Honda called for the agency to immediately stop publicly disseminating its ATV-related injury and death estimates, because it believed that the estimates state or imply that ATV's are causing the injuries and as such the public release of this data is unfair and misleading.[55] American Honda stressed that its own review of 251 injury reports related to Honda products which are part of the CPSC's hazard analysis study indicated that "a substantial majority were associated with circumstances or rider behavior that either clearly rule out, or cast very serious doubt on ATV design or performance characteristics as a significant cause or contributing factor to the incidents."[56]

The CPSC response (dated October 3, 1985, from agency General Counsel Daniel Levinson) acknowledges that the NEISS-generated estimates concerning ATV-related injuries and reports of ATV-related deaths do not provide definitive causative information about these incidents. However, the agency maintained that the NEISS estimates are useful in defining the magnitude of a product-related safety problem and in identifying common accident scenarios.[57]

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[51] Ibid., p. 33.
[52] Ibid.
[53] Ibid.
[54] Ibid. Conversations with CPSC staff members reveal that data in the agency's preliminary report on its survey of ATV-related injuries also indicates: (i) approximately 95 percent of ATV-related injuries to youngsters under age 14 occurred when the child was not riding a so-called child-size ATV; and (ii) approximately more than 90 percent of deaths associated with ATV's where the victims were under age 14 occurred when the youngster was not riding a child-size ATV. The proposed industry voluntary standard for ATV's states that current industry practices regarding age labeling specify 14 years of age as the minimum age for riding adult size (i.e., over 70–80 cc displacement) models.
[55] September 9, 1985, letter; p. 1.
[56] Ibid.
[57] October 3, 1985, letter, p. 1.

The general counsel contended that the NEISS estimates serve a valuable public service in alerting the public to potential safety problems. With respect to ATV's, this alert may have been all the more meaningful because public release of the eight-fold surge in ATV-related injuries may have helped focus public attention on safer riding practices and thus prevented further injuries.[58] The letter states (referencing the agency ANPR and its public hearings) that the CPSC has not reached any final causal conclusions concerning the accidents associated with ATV's and the vehicle itself.[59] In short, the agency rejected Honda's suggestion that public dissemination of ATV-related injury and death statistics be halted.[60]

(3) Testimony at subcommittee hearing

At its May 21, 1985, hearing, the subcommittee received testimony, both written and oral, from 22 witnesses. Several witnesses called for immediate action to stem the continued toll of deaths and injuries, even while they commended the CPSC's data-collection and other activities.

Joseph Greensher, M.D., chairman of the American Academy of Pediatrics, Committee on Accident Prevention and Poison Prevention, stated that "[C]hildren under age 16 seem to be at the greatest risk attempting to control and stabilize the ATV's." [61] He continued:

> Our committee is concerned about whether teenagers can use these vehicles without undue hazard of injury. They require coordination, dynamic balance, quick reflexes, good visual and auditory perception, and also a good sense of judgment. These levels of skill and development maturity are often lacking in the younger age group of riders. Given individual variations, it is not possible for us to recommend an age at which children are capable of safely handling a motorized vehicle. It would not be unreasonable to limit use to the age group over 16 until we gain more knowledge.
>
> * * * * *
>
> The Consumer Product Safety Commission's announced plan of action to conduct hazard analysis, undertake engineering, human and mechanical analysis, to hold public hearings, to monitor voluntary industry standards and education is to be commended. But while the clock is going to run, children are going to be injured and are going to be killed. There are over 2 million vehicles now in use. The projection is 2½ million by the end of 1985.
>
> I feel that we have to take action now in spite of what can be called the data paralysis that exists. It is my opinion after 20 years of working in the injury prevention field that in good conscience what the situation calls for is an

[58] Ibid. p. 2.
[59] Ibid., pp. 2-3.
[60] Ibid., p. 3.
[61] Hearings, p. 28.

> immediate voluntary moratorium by industry on the sale of new ATV's while we are accumulating the necessary data to ensure acceptable safe use. This would be true, responsible industry cooperation.[62]

Dr. Greensher also dealt with several other important safety issues related to ATV use and regulation. First, he answered Congressman Craig's concerns about injuries from bicycles as compared to ATV injuries by claiming that substantial design and safety improvements have taken place in bicycles. He also maintained that if the injury and fatality toll on the 100 million bicycles now in use was extrapolated to the ATV-death and injury toll, considering the number in use, the ATV rate would "certainly . . . be totally unacceptable." [63]

Dr. Greensher also dealt with the problem of suggestive advertising and related the case of a 10-year-old who, after seeing a TV commercial aired in the Boston area showing a small Honda tractor riding up the side of a house, tried to duplicate the feat on his family's new ATV. Dr. Greensher continued:

> Not surprisingly, when he tried to pop a wheelie, to get the front of the ATV in the air, it overturned on him, it broke his arm, caused facial lacerations, a broken nose, a concussion, but luckily, no permanent injuries.
>
> * * * * *
>
> This is a very common phenomenon that we face as pediatricians. It is known as an Evil Knievel-type of behavior pattern; children imitating what they see in the media with this.
>
> The same week that this was aired, there was a "Hart to Hart" TV show on there that showed a very dramatic chase on two three-wheeled ATV's that I am sure will be a pattern that will also be duplicated. These were driven through wooden structured houses or driven finally into a swimming pool.[64]

Finally, Dr. Greensher stated that he did not have much faith in the traditional educational and voluntary methods to lessen the toll from ATV's. He said "the traditional approach," included:

> * * * developing safety guidelines for those who disregard the hazard warning, advising the use of helmets and protective clothing, developing regulations for safe use, safety performance, and demonstrable driver competence. Our experience with these efforts to curtail injuries from the two-wheel vehicles does not hold much promise of success using the traditional educational and voluntary methods to combat the ATV menace.[65]

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[62] Ibid., pp. 28–29.
[63] Ibid., p. 27.
[64] Ibid., p. 28. See also Rep. Craig's comments on the "Evil Knievel Syndrome" and his experience with it, Ibid., p. 57.
[65] Ibid., p. 29.

With respect to children, Dr. Greensher stated that in his experience, they don't read or heed warnings. The following exchange between Chairman Barnard and Dr. Greensher took place:

> Mr. BARNARD. Thank you very much, gentlemen.
>
> Dr. Greensher, your testimony, of course, dealt primarily with children, and of course that is your specialty, and that is what your particular academy has been involved in. Children under 14 years of age, do you believe that children are inclined to read these instructions and warnings in any detail even if they are capable of doing so?
>
> Dr. GREENSHER. No sir, I don't believe that they are capable of understanding them totally, nor do I believe that given the circumstances of them scooting around over rough terrain that they are going to recall what they had read. Our experience with trying to teach driving in the 16- and 17-year-old age group has turned out to be a catastrophe, much less in the 14 to 16.
>
> Mr. BARNARD. Dr. Greensher, if you turn children loose driving small compact cars, couldn't we expect to have the same ratio of accidents?
>
> Dr. GREENSHER. I would certainly expect that we would, yes. Their judgment is just not good enough to overcome peer pressure, the desire to excel in the use of the particular item. They are not using it to get somewhere, they are using it for the thrill. And the thrill is in driving it up.
>
> Mr. BARNARD. Are you familiar with warnings such as these that might appear on vehicles?
>
> Dr. GREENSHER. I am. I have seen those for a variety of products, Mr. Chairman.
>
> Mr. BARNARD. Do you think that that is sufficient in itself for a child 14 and under?
>
> Dr. GREENSHER. No sir, I believe that if we—no, it is not. I don't think that parents at the time that they purchase the vehicle consider that their child is going to get injured using it. I don't think that they carefully read this. I don't think that they carefully go over this with their children.[66]

At another point, Dr. Greensher stated that the most vulnerable age group "seems to be the 10-to-14 age groups. They are much more daring and they have a greater leeway away from parental supervision." [67]

With respect to alcohol abuse and ATV accidents, Dr. Greensher stated:

> The alcohol situation, No. 1, in regards to the younger children, certainly from 14 and under, is not a very great factor at all, coupled with the fact that I am sure that the alcohol abuse, be it for snowmobiles, be it for motorbikes, be it for the three-wheelers or the four-wheelers, is approximately the same. Yet there is a disproportionate

[66] Ibid., p. 52.
[67] Ibid., p. 63.

number of severe injuries with these three-wheelers. So there is more than alcohol involvement.[68]

Philip R. Fine, co-director of the Spinal Cord Injury Care System at the University of Alabama, echoed Dr. Greensher's comments. Dr. Fine stated that his experience dealt with the devastating and catastrophic injury of paralyzing spinal cord injuries. He noted that on a "national basis, the frequency of these kinds of injuries seems to have reached epidemic proportions and we believe something substantive must be done to curb the carnage." He continued:

> * * * It is not only humane to do so, it is cost-beneficial and fiscally prudent. The expense associated with the acute care, rehabilitation and life-long maintenance needed by many spinal cord injured persons, coupled with indirect costs resulting from lost opportunities for both the patient and their families make doing nothing about this problem a non-viable option. Simply, the price of not taking immediate action is too great to pay both in human and financial terms.[69]

Dr. Fine stated that he and his colleagues found "a disproportionately high number of spinal cord injuries resulting from three-wheeler or ATV crashes," and he described the exceedingly serious consequences of such an injury.[70] He also stated that he used the word "epidemic" with care, and that it meant a situation where the frequency of occurrence would be "beyond that normally expected." [71]

In summary, Dr. Fine added that:

> * * * We encourage comprehensive data collection by appropriate agencies so lawmakers will have adequate information for making decisions concerning operator age limits, necessary safety precautions, possible engineering modifications of the vehicle design to improve safety, requiring operator instruction, or to decide whether sales for recreational use should be limited.[72]

Referring to a recent study concerning ATV injuries and deaths in Alaska published in "Morbidity and Mortality Weekly Report" by the Centers for Disease Control, Dr. Fine emphasized the urgency for prompt action:

> * * * Beyond the human suffering, the enormous costs associated with acute care, hospitalization and in some cases the long-term maintenance of persons injured and disabled in ATV crashes reemphasizes the need for immediate promulgation of rules and regulations to govern the operations of ATV's.[73]

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[68] Ibid., p. 59.
[69] Ibid., p. 43.
[70] Ibid., p. 35.
[71] Ibid., p. 52.
[72] Ibid., p. 43.
[73] Ibid., 51.

This Alaska study, conducted jointly by the State of Alaska's Division of Public Health and the Centers for Disease Control (CDC), was submitted to the subcommittee both by Hon. Bill Sheffield, Governor of the State of Alaska and by Ms. Susan Halbert, program coordinator, 4-H Youth Development of the University of Alaska's Cooperative Extension Service. Both Mr. Sheffield and Ms. Halbert emphasize Alaska's high per capita ownership and use of ATV's, reflecting their State's need for this mode of transportation in rural Alaska which often lacks road systems.

The authors offer a reasoned judgment as to underlying causes of ATV injuries and deaths as well as a proposed course of action:

> Potential risk factors for injuries associated with ATV's include alcohol use, ineffective helmet use, rider inexperience and inattention, and excessive speed. Of major importance is the finding that 12 (60%) of the fatalities [0.5% of the total fatalities] may have been prevented by wearing a helmet. These factors, as well as vehicle-use patterns and vehicle characteristics, must be evaluated as part of a rational approach to plan intervention strategies * * *[74]

Mr. Roy Janson, president of the American ATV Association, echoed Ms. Halbert's views in testifying that the major problems related to three-wheel ATV injuries are the failure of users to wear proper safety equipment while operating ATV's and using these vehicles in areas not recommended for ATV recreation.[75] He contends that these problems are increased when young ATV operators are allowed to use ATV's without close adult supervision.[76] Mr. Janson stated that while failure to wear appropriate safety equipment may rarely be the cause of an accident, the use of such equipment clearly can reduce the severity of injuries associated with motorized recreation.[77] He believes that "[u]ser education and information programs are clearly the most effective means for addressing the problems relating to misuse."[78] Mr. Mike Bishop, chairman of the California Off-Highway Motor Vehicle Recreation Commission, concurred. He testified that a majority of accidents in California parks were caused by excessive speed, unsafe turns, or drunk driving.[79] Also, he noted that many of the casualties did not have safety equipment and that a majority of the accident reports indicated that inexperience with the vehicle was a major contributor of accidents.[80] The ATV accident statistics compiled in California dictate a need for "public awareness, user participation, and actual education" which the California Commission is attempting to provide.[81] This commission is also proposing mandatory helmet legislation for their State vehicular recreation areas.[82]

The subcommittee also heard testimony from Timothy F. Scanlon, an attorney who represented John McKinley who received a

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[74] Ibid., p. 313.
[75] Ibid., p. 111.
[76] Ibid.
[77] Ibid.
[78] Ibid.
[79] Ibid., p. 114.
[80] Ibid., pp. 114, 117.
[81] Ibid., pp. 115, 118.
[82] Ibid.

$2.6 million jury award for damages resulting from an ATV accident. Mr. Scanlon stated:

> Notwithstanding the claims and denials of the manufacturers, the fact is that these 3-wheeled vehicles are simply more dangerous than the ordinary person expects. Safe and successful operation, especially on un-level terrain, requires proper shifting of the rider's weight forward or backward when going uphill or downhill, and requires side-shifting of the rider's body and proper distribution of his weight when turning.
>
> * * * * *
>
> These accidents are not happening because riders do not possess "ordinary" skills or because they do not exercise "ordinary" care. These accidents are happening precisely because most riders are persons of ordinary skill, care, and judgment.
>
> These products have been promoted in this country as safe and suitable for operation on all kinds of terrain. They are neither safe nor suitable for such operation, except in the hands of the most skilled riders, and even then, danger of overturning in one direction or another is a constant companion.
>
> These products have been promoted in this country as safe and suitable for operation by men, women, and children of nearly all ages, without any real indication of the nature and degree of skill required. They are neither safe nor suitable for operation by unskilled riders, and particularly, by young riders.[83]

The subcommittee also received testimony from Sherwood B. Menkes who also testified at the McKinley trial. Prof. Menkes stated as follows:

> There is serious risk of death and disabling injury in the use of an ATV. . . . The accidents arise because of the following factors:
>
> a. To some extent, the ATV is advertised as a vehicle which can be used to perform useful tasks in a rural environment, but the strong emphasis is on how much fun it is to ride it.
>
> b. Its appearance encourages the illusion of safety, because it does look like an overgrown tricycle. The large, balloon-like tires heighten the illusion.
>
> c. In fact, however, the ATV is inherently unstable in a number of ways which are described in greater detail in the next section.
>
> d. These instabilities cause accidents. The operating manuals describe some of the possible accidents, and suggest that they can be avoided by understanding the mechanics of the vehicle, and by developing certain skills in riding it. In fact, however, the necessary ma-

[83] Ibid., pp. 72-74.

nipulative skills are extemely complex, and, in my opinion, not easily acquired by the average rider.

e. Furthermore, in the actual use of the vehicles over rough terrain, the unexpected encounter with a dangerous situation requires a split-second instinctive response, which is beyond the ability of all but a very few talented individuals.

f. Finally, as will be seen, the nature of the instabilities is such that the vehicle will follow the trajectory of the thrown rider, and land on top of him or her, seriously aggravating the accident result.[84]

The subcommittee heard testimony from several accident victims and the parents and spouses of other victims concerning their personal experiences. One of the most poignant was the testimony of Janet Vance, whose son was severely injured. She described the kind of information the dealer supplied when she and her husband purchased ATV's:

> We were told that because the ATC was so heavy it was very difficult to flip it on steep hills or to tip it over in turns. We were told that they had sold many ATC's in our area, and we were given examples of people with mountain farms who had bought ATC's. On speed, we were told that there was a screw that could be adjusted for low-speed usage. We were told that they had heard of no injuries and they had sold a lot of ATC's.
>
> * * * * *
>
> If we had heard one warning, one indication of the danger we were placing our children in, we never, ever would have bought an ATC.
>
> * * * * *
>
> * * * Everyone who knew Bob and knew that he had always been an intelligent, cautious child recognized the truth when we said that no child, however skilled, is equipped to handle a machine that is so unstable and yet so powerful and heavy.[85]

Other victims of accidents also testified about exaggerated advertisign claims,[86] and about the victims' experience and safety consciousness.[87]

The subcommittee also heard testimony from each of the four major ATV manufacturers: American Honda Motor Company; Yamaha Motor Corporation, U.S.A.; Kawasaki Motors Corporation, U.S.A.; and U.S. Suzuki Motor Corporation. American Honda Motor Company, developer of ATV's and now the primary manufacturer, presented an extended discussion of the development of the Honda ATC, the growth in sales and usage, the development of its safety programs, its work on voluntary standards, and riding

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[84] Ibid., pp. 80–81.
[85] Ibid., pp. 12–14.
[86] Ibid., pp. 17, 28.
[87] Ibid., pp. 15–16.

ATV's.[88] With respect to the major cause of accidents, Honda contends:

> Through its experience, Honda began to focus on the major causes of accidents. These can be generally labeled as inappropriate rider behavior and misuse of the ATC. People were drinking alcohol and operating ATCs intoxicated, resulting in accidents. Riders were driving without proper safety equipment, such as helmets and boots, resulting in increased head and lower leg injuries. Riders were allowing passengers to ride with them, even though both the ATC and its manual clearly informed them that it is an operator-only vehicle. This resulted in loss of control and injuries to both the operator and to the passenger. Certain individuals were riding on inappropriate terrain, such as paved surfaces. Since the vehicle is designed for off-road terrain and incorporates the soft tires discussed above, this misuse resulted in loss of control and accidents. Children were allowed to operate without adult supervision in terrain which was above their ability. This, unfortunately, resulted in accidents to children, even though the manual on the child's ATC 70 machine instructs the parent to supervise the child's riding activity. Children were also found to be riding adult size machines. Because of their lower weight and smaller size, the children were unable to control the machines, resulting in accidents and injuries.
>
> The ATC was sold from the beginning with an instruction manual which told the rider to study carefully and practice the techniques required to operate the ATC before he increased his speed or rode on challenging terrain. Nevertheless, some people ignore the instructions and do not learn the proper skills necessary for operating this machine in off-road terrain. This resulted in misjudgments, and excessive speed for conditions, leading to accidents and injuries.
>
> Although all of these possible rider behavior problems had been addressed in the instructions and Owner's Manual accompanying each product sold, the accidents showed that the message was not heeded by the ATC owners and riders.[89]

All the manufacturers maintained that the ATV is not at fault for the surge in ATV-related injuries and deaths. All four companies contended that inappropriate rider behavior is the major cause of ATV accidents.[90] The behavior patterns cited as causing ATV-related accidents included: Use of alcohol while driving an ATV; driving an ATV without the proper protective safety equipment such as helmets and boots; riding an ATV with passengers; riding an ATV at an excessive speed for a particular terrain; children

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[88] Statement of American Honda Motor Company, Inc., Hearings, pp. 236–263.
[89] Ibid., pp. 248–249.
[90] Ibid., pp. 248–49, 266–67, 277–78, 287.

riding without adult supervision; and children riding vehicles that were too large for them.[91]

The manufacturers detailed their early commitment to improving ATV safety, highlighting the inception of the SVIA in 1983.[92] A key aspect of the SVIA program is a rider training course using certified instructors. American Honda contended that "we already have evidence . . . that training in the use of this vehicle is effective in reducing accident rates."[93] According to material provided by the SVIA, this course for new ATV users initially called for 20 chief instructors who were certified on March 3, 1985. They in turn were to train a cadre of an additional 1,000 instructors during 1985. All told, in 1985 some 40,000 ATV users would then be exposed to the 4½ to 6 hour long SVIA course which covers protective gear, controls, pre-ride inspection, local laws, safe riding practices, strategies for riding on a variety of different terrains, starting and stopping an ATV engine, principles of turning, climbing and descending hills, emergency maneuvers and riding over obstacles.[94] Corollary training by various organizations in both the public and private sectors will "by 1986 most likely reach another 40,000 riders and increase materially in the out years as additional organizations become involved."[95] Although training is agreed to be an important aspect in reducing deaths and injuries, only a very small percentage of all new ATV riders will be trained by SVIA certified instructors under the present schedule. In fact, in 1985 the SVIA training program has at best trained 4,000 to 5,000 persons, compared to its goal of training 42,000 ATV users. SVIA has also made clear that it will fall considerably short of reaching its previous goal of training another 40,000 riders in 1986.

Other key aspects of the multi-faceted SVIA safety program emphasized by the representatives of the four major ATV manufacturers included their respective endorsement of the ongoing effort by SVIA (in cooperation with the CPSC) to develop a voluntary safety standard for ATV's[96] and a commitment to SVIA's advertising guidelines which display only responsible ATV use.[97] The advent of age labeling (to make clear that full-size vehicles are clearly marked not for use by chidren under age 14) was also announced by each company for 1986 models.[98] However, age labeling has not been made a requirement under the draft ATV voluntary safety standard.

With respect to the work being done by the industry on the "voluntary standards for all aspects of the performance by the ATV vehicles" cited by American Honda in its statement before the subcommittee,[99] Commissioner Statler commented:

> If the industry is doing any work to mitigate deficiences in the 3-wheeled configuration of the ATV itself, it's being

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[91] Ibid.
[92] Hearing, op. cit., p. 248–50; 267; 284; 289–290.
[93] Ibid., p. 255.
[94] February 10, 1985 briefing package, op. cit., pp. 255, 267, 284, 290–291.
[95] SVIA letter of March 15, 1985.
[96] Hearings, pp. 255, 267, 284, 290–291.
[97] Ibid., pp. 25, 367, 283–84, 292–94, 370.
[98] Ibid., pp. 254, 280, 289, 293–294.
[99] Ibid., p. 255.

kept a secret. In fact, it wasn't until recently that the SVIA grudgingly agreed even to work on a voluntary safety standard. On April 12, 1985, in a letter to the Commission, the SVIA proclaimed its "progress" and willingness to have its draft working document ". . . expanded and revised to include additional items and language that would result in a truly new set of industry practices." But conspicuously missing from the list of subjects to be worked on was the paramount consideration needing to be addressed—the machine's stability while in motion. The industry standard would address all of 22 listed items including "handlebar shielding," "tire gauge," "size, weight and location of racks . . . (and) hitches," and "flag bracket"—even though there's no indication that any of these items was ever responsible for a single death or injury. The list even included "static stability" despite the fact that no one has alleged, to my knowledge, that an ATV may be dangerous when it's at rest.

But oddly, not a single mention by the industry of their proposed standard addressing the crux of the problem? Namely, *dynamic stability* and *handling*—that is, the tendency of the vehicle to be unstable when moving over uncertain terrain at high speeds. Not even an allusion to it! [100]

Since this statement was made, the SVIA has informed the Commission that the voluntary safety standard which is presently under consideration will address dynamic stability and handling of ATV's. However, the committee has been informed that no timetable has been set for this additional standards development work. In addition, the committee is of the view that the testing scheme currently proposed to determine dynamic stability and handling characteristics of ATV's is inadequate.

In summary, two important items cited by the industry as helping to reduce accidents and deaths—training and the development of a voluntary standard—will not yield significant results in the immediate future. SVIA's training program is simply too small to deal with the number of new riders and others who have never had adequate training. Moreover, the program is falling far short of its goals. Finally, the voluntary standards process is exceedingly slow, and no results appear close even after more than 1 year during which the process has operated.

B. THE COMMISSION'S RESPONSE

The CPSC began investigating the upward spiral of ATV-related injuries and deaths in early 1984, following a surge reported by the NEISS. This NEISS warning led the CPSC's Directorate for Compliance and Administrative Litigation and its Product Safety Assessment team in spring 1984 to begin an investigation of ATV's.[101] Staff members began examining various economic, epi-

[100] Ibid., pp. 197-198.

[101] Memorandum to the Commission dated March 12, 1985, from Nick Marchica, Subject: "All Terrain Vehicles ATV's" (hereinafter March 12, 1985, memo), p. 1.

demiologic, engineering, human factors and medical aspects of ATV safety. In addition, Commission staff investigated accidents reported to have involved ATV's. CPSC staff also held several meetings with the Specialty Vehicle Institute of America (SVIA), a trade association representing manufacturers and distributors of ATV's and with individual manufacturers of ATV's.[102] At a meeting held on October 23, 1984, the SVIA proposed a number of actions to reduce ATV-related injuries, in the main through rider education and training. In January 1985, the industry provided further details of the progress of its rider education and training program. In December 1984 and March 1985, the Commission and the SVIA jointly issued safety alerts warning consumers of the potential risks associated with ATV's.

With the rapidly increasing number of injuries and deaths associated with ATV use, the Commission decided to assess possible actions. On February 26, 1985, the Commissioners were briefed by Commission staff concerning updated accident statistics, industry activities, including the industry's expressed desire to work on industry practices,[103] and pending CPSC staff efforts on ATV-related work. As a result of that meeting, the Commission directed the staff to prepare a listing of possible ATV safety options for Commission consideration for fiscal year 1985.[104]

Commission staff identified nine options, focusing on three areas: (1) Information and education efforts to publicize the awareness of potential ATV hazards and safe riding methods; (2) technical work to obtain detailed information to determine causal factors related to ATV accidents, to investigate specific performance characteristics of existing ATV's, to identify safer performance characteristics for ATV's in use, and to evaluate the ability of users at various ages to maintain control of ATV's under different terrain and speed conditions; and (3) standards development activities concerning ATV's under the auspices of a national voluntary standard organization.[105] One of the nine options presented involved prosecutorial action by the CPSC under section 15 of the Consumer product Safety Act to redress a possible substantial product hazard presented by ATV's.[106] The nine options presented to the Commission are set forth in the memorandum to the Commission dated March 15, 1985, contained in the appendix to the subcommittee's hearings.[107]

Commission staff expressly recommended that a mix of these options was needed to address the problem of escalating ATV injuries and deaths.[108] Two courses of action were recommended. One approach comprised those options encompassing information and education, technical work, and standards development.[109] The other approach focused on the needed technical work, postponing the Commission's decision on how to address the ATV problem to mid-

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[102] ANPR, Federal Register, May 31, 1985, p. 23140.
[103] SVIA letter of March 15, 1985, p. 3.
[104] March 12, 1985, memo, p. 1.
[105] Ibid, pp. 1-3.
[106] Memorandum to the Commission dated March 13, 1985, from David Schmeltzer, p. 1.
[107] Hearings, pp. 353-378.
[108] March 12, 1985, memo, p. 4.
[109] Ibid., p. 5.

year in fiscal 1986.[110] The Commission also reviewed material prepared by staff concerning the feasibility of bringing an action under section 12 of CPSA, which authorizes the agency to bring suit against an imminently hazardous product for seizure and condemnation or against any person who is a manufacturer, distributor or retailer of such product or against both.[111]

Following a thorough review of the available data and an assessment of the options presented by staff, on April 3, 1985, the Commission unanimously voted to commence a rulemaking proceeding by issuing an ANPR under the authority of section 9(a) of the Consumer Product Safety Act and the authority of section 3(f) of the Federal Hazardous Substances Act.[112] At that time, the Commission made ATV safety a priority project for FY 85 and also adopted a number of other measures intended to assist in obtaining further information on the hazards associated with ATV's. These measures, to be undertaken by Commission staff under the guidance of a special staff task force, include:

(1) Conducting surveys of ATV injuries and consumer exposure to ATV's to obtain detailed information on ATV's and to prepare a hazard analysis.

(2) Conducting engineering, human factors, and medical analysis of the hazards associated with ATV's and their use.

(3) Monitoring the development of any voluntary standards for ATV's, pending review of future data and industry activity.

(4) Conducting a series of public hearings to solicit safety-related information on ATV's.

(5) Sharing information with user groups and State, local, and Federal officials.

(6) Monitoring the ATV industry's education and training effort, reserving the right to assist or strengthen the industry effort.[113]

In issuing the ANPR, the Commission reached a preliminary determination that there may be an unreasonable risk of injury associated with the use of all-terrain vehicles.[114] The ANPR specifies that it is but the first stage in the Commission consideration of what regulatory action, if any, to take with respect to ATV's.[115] The Commission stated that it may decide to pursue alternatives other than rulemaking to address risks associated with ATV's. The agency specifically invited public input on a wide range of issues.

As of the close of the comment period for the ANPR (which was extended to September 30, 1985), 3,003 comments were received.[116] The ATV Task Force is in the process of reviewing and summarizing these comments in conjunction with the information received at the CPSC-sponsored public hearings on ATV safety held to date.[117]

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[110] Ibid.
[111] Memorandum to the Commission dated March 28, 1985, Subject: "ATV Options: Section 12 and 27 of the CPSA," pp. 1-9.
[112] ANPR, op. cit., p. 23140.
[113] Ibid., p. 23139.
[114] Ibid.
[115] Ibid., p. 23143.
[116] November 4, 1985, Status Report from CPSC ATV Task Force, p. 2.
[117] Ibid.

Since April 1985, the CPSC ATV Task Force (which includes staff engineers, human factor specialists, public affairs specialists, epidemiologists, and attorneys) has engaged in a variety of activities. Five public hearings have been conducted as follows: Jackson, MS, May 30, 1985; Dallas, TX, June 17, 1985; Concord, NH, July 25, 1985; Milwaukee, WI, September 3, 1985; and Los Angeles, CA, October 17, 1985. A sixth public hearing in Anchorage, AK, was held in March 1986. All of the hearings were well attended and provided a substantial amount of ATV user, dealer, and manufacturer input, enhancing the Commission's growing array of injury, engineering, medical and epidemiological information. State and local government representatives also participated. The Commission, including members of the ATV Task Force, testified at the subcommittee's May 21, 1985, hearing on the CPSC's response to hazards of all-terrain vehicles as well as responded to numerous questions submitted by the subcommittee.

The Commission voted to make ATV safety a priority project for fiscal years 1986 and 1987, ensuring that this project will receive adequate funding in a time of tight budget constraints. To date, in FY 86, the Commission has continued its series of public hearings. Preparation and analysis of ATV exposure, economic, engineering, human factors, and medical analyses are proceeding with the goal of completing all planned evaluation and technical work in FY 86. These technical analyses will form the basis for staff recommendations concerning the various regulatory and nonregulatory options for Commission consideration to address hazards associated with ATV use. The staff recommendations and related options package is slated for delivery to the Commission by the end of September 1986 which is the end of FY 86,[118] for implementation in FY 87. Possible alternative Commission actions are discussed below.

As implicitly revealed in the Commission's planning documents, much emphasis is placed on the development of a voluntary safety standard for ATV's. Commission staff were directed to monitor the industry's development of such a standard—a move by industry which reflected a change from its initial position indicating development only of an "industry recommended practice."[119] The initial draft proposal by SVIA concerned only standardization of controls.[120] The CPSC staff and the SVIA met on April 26, 1985, to initiate development of a voluntary standard. A series of consultations and meetings have followed, which included the Commission's assistance in reaching an accord with the American National Standards Institute (ANSI) to expedite the processing of the draft standard.

The first version of the voluntary safety standard covers: The types and sizes of ATV's; required equipment (including standardization of controls); necessary safety labeling; requirements pertaining to ATV owner's manual; educational materials; and training

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[118] Commission's FY 87 Budget (January 1986), p. 82; Supplementary Budget Materials, p. D-18.

[119] SVIA March 15, 1985, letter, op. cit.

[120] SVIA letter dated March 15, 1985, attachment.

information.[121] A key area, dynamic stability of an ATV, was reserved for a later edition of the proposal standard.[122]

The draft standard was sent out for public comment on August 16, 1985. The CPSC's Task Force comments were sent to the SVIA on September 18, 1985.[123] However, on January 21, 1986, the SVIA informed the Task Force that the draft standard would have to be reballoted for public comment as a result of changes made to the August 16, 1985, edition of the standard in response to comments received. Although most of the changes relate to definitional terms, ANSI procedures require the reballoting procedure.[124] The reballoting will cause a delay in the effective date of the voluntary standard to include the 1988 model year ATV's instead of the 1987 model year as originally stated in the draft voluntary standard.[125] However, the Task Force Chairman was told that the four SVIA member manufacturers (Honda, Kawasaki, Yamaha and Suzuki) will meet the intent of the original draft standard in producing their 1987 ATV models.[126]

The ATV Task Force keeps the Commission informed of the progress of the voluntary standard effort in a monthly status report. Sufficient information should be available to the Task Force concerning the scope and pace of the voluntary standard effort for inclusion in its options briefing package scheduled for completion in late September 1986.[127]

Other activities undertaken by the Commission include analysis of numerous confidential documents requested to be furnished on a voluntary basis by American Honda Motor Company, Yamaha Motor Corporation, U.S.A., Kawasaki Motors Corporation, U.S.A., and U.S. Suzuki Motor Corporation and their parent corporations in Japan.[128] The Commission, through documentation submitted through the ATV Clearinghouse and otherwise, is assessing ATV-related information provided by matters pending in litigation, or settled, or resolved by the judicial process.[129]

As indicated, the Commission has been actively engaged in examining the safety issues associated with all-terrain vehicles since early in 1984. It has ordered an indepth staff review of these issues scheduled to be completed by the end of September 1986. It has begun a rulemaking process and has instituted various other measures. If the Commission proceeds on its present course, it is likely that no action will be taken to lessen deaths and injuries resulting from ATV use for perhaps another year. In the interim, the death and injury toll will continue to grow. One argument given for this prolongated process is that the Commission requires more data in order to act. It is the committee's view, however, that the data already exists to require that the Commission act now under its empowering statutes. It is likely that any enforcement action taken by the Commission will be opposed by the industry in court, and the

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[121] ANSI Draft Standard for ATV's.
[122] Ibid., section 8.2.
[123] September 26, 1985, Status Report from CPSC ATV Task Force, p. 3.
[124] Memo from Nick Marchica to Commission dated February 10, 1986.
[125] Ibid.
[126] Ibid.
[127] Ibid.
[128] Interview with ATV Task Force member.
[129] Ibid.

CPSC wishes to create as extensive a record as possible to fortify its position in any case which may be brought. Nevertheless, the committee believes that the plain mandate of the laws under which the CPSC operates requires action now. It therefore recommends that the Commission take action now under section 12 and section 15 of the CPSA.

1. Options available to the Commission

By issuing the ANPR, the Commission commenced a rulemaking proceeding to address the potential unreasonable risk of injury associated with the use of both three- and four-wheel all-terrain vehicles.[130] The ANPR was issued under section 9(a) of the Consumer Product Safety Act (CPSA),[131] and the authority of section 3(f) of the Federal Hazardous Substances Act (FHSA).[132]

The Commission, however, retains various regulatory and nonregulatory alternatives, since the ANPR represents only the first stage in the agency's consideration of what regulatory action, if any, to take with respect to ATV's. These remedies include rulemaking; public notice of hazards associated with an ATV; repair of an ATV; replacement of an ATV; refund of an ATV's purchase price; imminent hazard suits; requirements for submission of information; and miscellaneous compulsory process.

Although the exact wording is different in each case, the common prerequisite for Commission action before it may use its enforcement powers is some finding that the product presents an *unreasonable* hazard or that it presents an *unreasonable* risk of injury or that a substantial product hazard exists. This involves a matter of judgment, a balancing test, or a weighing of benefits against risks of the kind done every day by members of regulatory commissions, by courts and by Members of Congress. In the committee's view, an adequate data base now exists for making this determination. The Commission has failed to exercise its powers. Accordingly, we recommended that it be directed to do so.

In making a judgment of reasonableness, all relevant facts and circumstances, including the level of deaths and injuries associated with ATV use, when factored by the likelihood of injury, must be weighed against the harm the regulation may impose on manufacturers and consumers. The most important consideration, however, must be the preservation of the public's health and safety, which is the reason for the CPSC's existence. In the committee's judgment, a finding of unreasonable hazard is called for. As indicated earlier, the level of deaths and injuries associated with ATV's outpaces the level attributable to any other consumer product known to the committee which resulted in a voluntary or mandatory recall. Moreover, the rates of injuries associated with ATV's outpaces that for other off-road vehicles used for recreational purposes. As the Commission's ANPR noted:

> The rate of injuries associated with ATVs were nearly double those for mini bikes and trail bikes and more than

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[130] ANPR, pp. 23139-23140.

[131] Ibid., p. 23140. (15 U.S.C. 2058(a)) The procedural and substantive requirements for issuance of an ANPR are identical under section 9(a) of the CPSA and section 3(f) of the FHSA.

[132] Ibid. (15 U.S.C. 1262(f))

> eight times those for snowmobiles. The hospitalization rate for ATVs is more than twice that of mini bikes and trail bikes. Injuries associated with these other types of vehicles for off-road use have remained about the same from 1983 to 1984, while ATV injuries have increased.[133]

Finally, much emphasis is placed on the role of rider misuse in accidents, but the conclusion is clear that an unacceptable level of accidents occurs regardless of rider misuse. The Commission concluded:

> The basic configuration of the ATV and its unique performance characteristics, including dynamic stability and handling, appear to play a major role in accidents involving ATVs. Many of the serious injuries and deaths reported in the in-depth investigations resulted from loss of control of the ATV and were observed regardless of whether alcohol, riding double, or speeding were also observed. These incidents involved drivers of all ages. Also, although some victims were first time ATV users, many had previous experience riding ATVs and experience riding motorcycles or minibikes. While drivers of all age groups have been injured or killed in ATV related accidents, a great many fatalities and injuries involve children.[134]

The following factors, among others, were considered by the committee in making its determination that an unreasonable risk of injury presently exists: (a) the high rates of deaths and injuries among young children who are unable or unwilling to accept warnings; (b) the exceedingly slow pace both of voluntary training efforts and the development of a voluntary standard; (c) the unique physical and handling characteristics of ATV's which make them appear to be safer than they are and which require substantial levels of skill and strength to operate them safely; (d) the reason to believe that no standard or change in the design of the three-wheel vehicle would result in an improved safety record without also changing the recreational uses to which the ATV's are now put; (d) the evidence that some advertising and promotion efforts have encouraged misuse and the evidence that significant numbers of riders are unaware of the hazards associated with ATV use and have not received adequate training; (e) the evidence that helmet use does not substantially lessen the risk of serious spinal cord and other injuries; (f) the evidence that even experienced riders who have not engaged in rider misuse often are the victims of fatalities and serious injuries; and (g) the fact that State laws are inadequate to deal with the problem and are not likely to impose greater safety requirements in the immediate future.

On the question of loss to manufacturers and consumers, the fact that ATV's are used primarily for recreation and leisure activities must be weighed heavily on the side of eliminating the continuing toll of deaths and injuries. Unlike a pharmaceutical medicine or other necessary commodity, the use of an ATV is almost never nec-

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[133] ANPR, p. 23141.
[134] Ibid.

essary for the health or livelihood of the user. It is used primarily for sport and recreation. It is the view of the committee that, given the high toll taken by the use of these vehicles, other less dangerous forms of recreation and sport can be substituted by the user at a lower social cost.

(a) Rulemaking

Under section 7 of the CPSA, the agency is authorized to promulgate a mandatory consumer safety standard which sets forth certain performance requirements or which sets forth certain requirements that a product be marked or accompanied by clear and adequate warnings.[135] The statute requires that a performance, warning or instruction standard must be reasonably necessary to prevent or reduce an "unreasonable risk" of injury. This determination involves a balancing test. Section 7's legislative history indicates that an unreasonable risk is one where the hazard can be prevented or reduced without affecting the product's utility, cost or availability or one where the need to protect from the hazard associated with the product outweighs the effect of the rule on the product's utility, cost or availability.[136]

The courts have also interpreted the term "unreasonable risk." In order for a risk to be deemed "unreasonable," the Commission must show that "the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation imposes upon manufacturers and consumers."[137] This means that the regulation's benefits must bear a reasonable relationship to its costs.

In addition, if the Commission finds that no feasible consumer product standard under section 7 would adequately protect consumers from an unreasonable risk of injury associated with ATV's, the Commission may promulgate a rule under section 8 of the CPSA declaring some or all ATV's to be banned products.[138] In the case of ATV's, there is some reason to believe that a "technical fix," in the form of a standard, may not be possible without changing the purposes and present uses of ATV's. Sherwood Menkes testified as follows:

> I have been asked to respond to the question: "is a technical fix possible to improve safety of ATV's?" * * *
>
> Two directions in which to go could be (i) to make it a 4 wheeler, and (ii) to lower the center of gravity of the rider. Other possibilities would include (iii) speed limiting features, and (iv) consideration of a limited slip differential.
>
> What is really needed is such a marked change in the design that it is likely the result would not sell.[139]

Commissioner Statler has maintained that:

> * * * one must *induce instability* in order to be able to turn the vehicle. The rider is effectively riding on two

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[135] ANPR, p. 23140 (16 U.S.C. 2056).
[136] House Report No. 92-1153, p. 33.
[137] *Gulf South Insulation et. al.* v. *CPSC*, 701 F. 2d 1137, (5th Cir. 1983). *Southland Mower Co.* v. *CPSC*, 619 F. 2d 499, (5th Cir. 1980). *Aqua Slide 'N' Dive* v. CPSC, 569 F. 2d 831 (5th Cir. 1978).
[138] ANPR, p. 23142 (15 U.S.C. 2057).
[139] Hearings, p. 88.

> wheels at that point of the turn and, depending on how much weight is thrown to the outside of the turn, the rider may cause the vehicle to flipover or rollover because of the delicate handling that is required. Again, that's hardly a maneuver one can expect of a youngster under 12 or 14, and often as young as 5 or 6 or 7 years of age. I have a hard time understanding why the manufacturers would deny a fundamental operating procedure that is spelled out in their own owners' manuals.[140]

In its testimony before the subcommittee and in other places, Honda has described the methods by which the ATV was designed and has expressed its belief that it has now developed the safest design possible for the uses intended for the vehicle.[141] On February 15, 1985, CPSC engineering staff met with Honda representatives including the principal inventor of the ATC, Mr. Osamu Takeuchi. In a memorandum to the Commission dated March 29, 1985, the CPSC's engineering staff's discussion with Mr. Takeuchi is described in detail. The conclusion of the discussion is stated as follows: "Apparently, 'fine tuning' of the designs is still an ongoing effort, but Mr. Takeuchi is satisfied that no further significant development is possible."[142] In another memorandum, in which the Commission's engineering staff concluded that "the dynamic stability characteristics of the ATV comprise the single most prominent factor identifiable as a cause of loss of control," the staff commented:

> Engineering Sciences has to date only touched upon the broader question of the feasibility of changing the basic configuration of the machine to provide it with a greater degree of dynamic stability, while maintaining its current functional utility. We have held limited discussions on this subject, with somewhat inconclusive results. Representatives of the four major Japanese manufacturers maintain that considerable development lies behind the present configuration, and that *no modifications remain to be explored which would not render the machine useless.*[143]

Accordingly, the committee has concluded that it is unlikely that either the Commission or the industry will be able to devise a voluntary product standard which will result in lessening the death and injury toll from ATV's. For these reasons, the committee believes the CPSC should move under section 8 declaring ATV's to be banned products as soon as its studies confirm that no feasible consumer product safety standard would adequately protect the public from the unreasonable risks associated with ATV use.

If it is determined that some or all ATV's are articles intended for use by children, under section 3(e) of the FHSA, the Commission may promulgate a rule declaring all ATV's, or certain ATV's

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[140] Ibid., p. 207. The owners' manuals to which reference is made are contained at Hearings, pp. 215–222.

[141] Ibid., pp. 232–263.

[142] Memorandum to the Commission, dated March 29, 1985, re ATV Meeting Log. Contained in subcommittee files.

[143] Memorandum to the Commission dated February 20, 1985, contained in subcommittee files. (Emphasis added.)

which do not meet specified requirements, to be hazardous substances because, during normal use or when subjected to reasonably foreseeable damages or abuse, they present a mechanical hazard as defined in section 2(s) of the FHSA.[144] An article intended for use by children which has been declared by rule to be a hazardous substance is banned under section 2(q)(1)(A) of the FHSA.[145]

The statutorily mandated procedure for promulgating a mandatory safety standard is specified in section 9 of the CPSA,[146] and section 3(f) of the FHSA.[147] The ANPR represents the first step in a regulatory proceeding that could lead to a safety rule for ATV's under either section 9 of the CPSA or section 3(f) of the FHSA. The second step is the issuance of a proposed rule followed by public comment.[148] The third step is the issuance of a final rule.[149] If the Commission decides to proceed with a mandatory standard, its staff could develop a proposed rule. However, any interested person may submit an existing standard as a proposed mandatory safety standard.[150] In either case, the Commission would proceed with a proposed and a final rule, under the second and third rulemaking steps.

However, the Commission may not find it necessary to reach the second and third steps. As required by the CPSA, the FHSA, and its own policies,[151] the Commission will not issue a regulation unless the alternative approaches for addressing the risk of injury presented by ATV's are not adequate to reduce or eliminate the risk. If the Commission determines that an alternative approach would be effective, it will terminate this rulemaking proceeding if it finds that a voluntary standard developed in response to this ANPR would eliminate or adequately reduce the risk of injury associated with ATV's, and that it is likely that there will be substantial compliance with the voluntary standard.[152]

Obviously, rulemaking is an involved, complex proceeding. Under the Commission's current timetable, an options paper detailing the compilation of its ongoing technical work and suggested staff recommendations for further regulatory or nonregulatory action will not be prepared until the end of fiscal year 1986.[153] The Commission's expectation is it will reach a decision concerning these as of yet undelineated options and implement its decision during FY 87.[154]

As indicated above, the Commission has commenced the rulemaking process by issuing an ANPR. It should move to the next step—the issuance of a proposed safety rule—without delay and not later than August 1, 1986. The proposed rule should deal with all the known hazards associated with ATV use and should focus on problems of dynamic stability disclosed in the indepth investiga-

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[144] Ibid. (15 U.S.C. 1261(s)).
[145] Ibid. (15 U.S.C. 1261(q)(1)(A)).
[146] Ibid. (15 U.S.C. 2058).
[147] Ibid. (15 U.S.C. 1262(f)).
[148] 15 U.S.C. 2058(c); 15 U.S.C. 1262(h)(a)(2).
[149] 15 U.S.C. 2058(d)(1)(2); 15 U.S.C. 1262(a)(2) (i)(1)(2).
[150] 15 U.S.C. 2058(a)(5); 15 U.S.C. 1262(a)(2) (f)(5).
[151] 15 U.S.C. 2058(b)(1)(2); 15 U.S.C. (a)(2) (g)(1)(2).
[152] Ibid.
[153] CPSC Staff Briefing Package on Priority projects dated June 12, 1985, Tab B.
[154] Ibid.

tions and other studies of ATV accidents. If, by August 1, 1986, it is determined that "no feasible consumer product safety standard . . . would adequately protect the public from the unreasonable risk of injury * * *," [155] then the Commission should proceed under section 8 of the CPSA to declare the product a banned hazardous product.

(b) Public notice of hazards associated with ATV's; repair of an ATV; replacement of an ATV; or refund of an ATV's purchase price

Section 15 of the CPSA provides that if the Commission determines that ATV's contain a product defect which, because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, presents a substantial risk of injury to the public ("substantial product hazard"), the Commission may order manufacturers, distributors, or retailers to take appropriate action to adequately protect the public.[156] This action may include giving public notice of the defect, mailing notice to any person known to have received the product, and ordering repair, replacement or refund of the purchase price of the product at the manufacturer's, distributor's, or retailer's election.[157]

Under section 15 of the FHSA, if the Commission believes that some or all ATV's are articles intended for use by children which contain a defect which creates a substantial risk of injury to children, the Commission is authorized to initiate an administrative adjudication seeking essentially the same relief and under similar constraints as it could obtain under section 15 of the CPSA.

Although most section 15 actions undertaken by the Commission are resolved voluntarily, this option under either the CPSA or FHSA could involve a four-stage appeal process. If contested, a section 15 case is initially tried before an administrative law judge. An appeal from the administrative law judge's order can be taken to the Commission. A further appeal can be taken to a district court and another appeal to a court of appeals.[158] The standard of review by the district court is whether there is substantial evidence on the record to support the Commission's finding of a substantial product hazard.[159] In other words, to succeed initially before the administrative law judge, complaint counsel for the Commission must prove there is a defect in the product which creates a substantial risk of injury.[160]

It should be noted that many proceedings begun by the CPSC under sections 12 or 15 result in voluntary action by the manufacturers thereby avoiding the necessity for the full legal proceedings outlined above. During the subcommittee hearings Mr. Craig asked

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[155] Section 8, CPSA.
[156] ANPR, p. 23142; 15 U.S.C. 2064(a)(b)(c).
[157] Ibid.; 15 U.S.C. 2064(d).
[158] 15 U.S.C. (f); 5 U.S.C. § 704.
[159] 15 U.S.C. 2064(a)(2).
[160] The Commission's regulations, 16 CFR § 115.4, concerning the definition of defect made clear that such a defect is not limited to a design defect or manufacturing flaw. As stated in this regulation: "A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions."

about the CPSC's court record in suits brought against products. Mr. Levinson, the CPSC's general counsel, replied as follows:

> * * * Most important * * * 99 percent of threatened actions do result in some form of negotiated settlement.[161]

In the case of ATV's the CPSC has not requested the industry to do anything voluntarily and, consequently nothing has been done in this manner. One Commissioner has stated the case of voluntary action as follows:

> Conscientious manufacturers should contact every existing ATV owner, apprise them of the rising incident rate, spell out the risks involved (especially to youngsters), and detail explicit safety precautions. Retailers should follow up with efforts to make sure this material is both read and understood.
>
> But beyond that, with the reams of evidence already gathered, I can't understand why any conscientious firm wouldn't take immediate action now—not months or years from now when a safety standard may finally see the light of day—to halt current production and sale of its 3-wheeled ATVs until satisfied that a far safer design is in the offing.
>
> * * * * *
>
> But, Mr. Chairman, let me emphasize that efforts aimed at improving future production, while they should be encouraged, may not be enough to effectively deal with the problem at hand, notwithstanding the push to promote driver training, age labeling, cautions, safety advertising, the 4-wheel model and technologically advanced 3-wheeled vehicles, the fact remains that there are in excess of one million earlier versions of 3-wheel ATVs already in use. These vehicles may pose a substantial risk of injury to consumers which will have to be addressed. If this can be accomplished through a repair or replacement program, that's fine. But depending on the Commission's upcoming assessment, complete or partial recall of "old-style" ATVs, by the Commission or by companies, may prove to be necessary.[162]

(c) Imminent hazard action

Section 12 of the CPSA authorizes the Commission to file an action in a U.S. district court against an imminently hazardous consumer product, against any manufacturer, distributor or retailer of an imminently hazardous consumer product or against both.[163] The court is empowered to grant such temporary or permanent relief as may be necessary to protect the public from the risk.[164] This relief can include notification of risk of injury or

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[161] Hearings, p. 224.
[162] Ibid., pp. 198-199.
[163] Ibid., 15 U.S.C. 2061(a).
[164] Ibid., 15 U.S.C. 2061(b)(1).

death to purchasers of the product, public notice, or recall, repair or replacement of the product, or refund of the purchase price. The district court's remedial powers are quite broad, and are not limited to notice, recall, repair or replacement. For example, a district court could order a manufacturer to offer consumers a training program as a condition of sale or any other form of equitable relief (prospective, retroactive, or both) it believed necessary.

Under section 12 of the CPSA, a suit brought against the manufacturer, distributor or retailer is an injunctive action seeking to restrain (or mandate) the performance of certain acts or practices. An action against the product, on the other hand, is an "in rem" proceeding where the court has jurisdiction over the product and not necessarily personal jurisdiction over the manufacturer. The remedy when a court asserts "in rem" jurisdiction is seizure of the product and not an order enjoining certain acts or practices of the manufacturer, retailer or distributor. Should there be insufficient basis for an American court to assume personal jurisdiction over any foreign manufacturers of ATV's, a section 12 action could be instituted seeking seizure of the products under this authority. Alternatively, if personal jurisdiction over the foreign ATV manufacturers was problematic, a section 12 action could be brought against importers and the American distributors and retailers of ATV's seeking relief other than seizure.[165]

An action instituted under section 12 of the CPSA generally requires less time to reach a final resolution than a section 15 action.[166] This is so because two levels of appeal (available under section 15) are eliminated in a section 12 proceeding. A section 12 trial is conducted in a district court and an appeal, if any, can be filed in a court of appeals.[167] The standard of review on appeal is also different. The applicable standard is whether the district court's findings are clearly erroneous.[168] In addition, a section 12 action may be filed "notwithstanding the existence of a consumer product safety rule applicable to such product, or the pendency of any administrative or judicial proceedings under any other provision of this Act."[169]

A section 12 action does not require the agency to prove that a product contains a defect. As noted, the section 12 standard of proof is that the product creates an imminent and unreasonable risk of injury. However, as a practical matter, the types of evidence necessary to prove a "defect" or "unreasonable risk" would be similar.[170]

Imminent hazard authority is also available to the Commission under sections 2(q)(2) and 3(e)(2) of the FHSA.[171] Under both of these sections, if the Commission finds that a hazardous product ((2)(q)(2)) or a children's article ((3)(e)(2)) presents an imminent

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[165] Memorandum dated March 28, 1985, to the Commission, Subject: "ATV Options: Sections 12 and 27 of the CPSA."

[166] This assumes that a jury trial is not permitted in a section 12 action. This issue is not entirely clear.

[167] 15 U.S.C. 2061(b)(1); Memorandum dated March 28, 1985, p. 7.

[168] Memorandum dated March 28, 1985, p. 7. This statement also assumes that a jury trial is not permitted in a section 12 matter.

[169] Section 12(a), CPSA; 15 U.S.C. 2061(a).

[170] Ibid., p. 8.

[171] 15 U.S.C. 2064(d); 15 U.S.C. 2061(b)(1).

hazard and publishes that finding in the Federal Register, the product is deemed to be a banned hazardous substance and its introduction into interstate commerce is prohibited until the rulemaking proceeding is completed.[172]

As noted in the Commission's ANPR, various data may indicate that certain or all ATV's are articles intended for use by children which may be subject to regulation under the FHSA.[173] If it is determined that some or all ATV's are intended for use by children, then the imminent hazard provisions of section 3(e)(2) may be germane.

This section provides that if the Commission finds that a children's article presents an "imminent hazard to the public health" because of a mechanical hazard and publishes that finding in the Federal Register, either before or during a rulemaking proceeding under provisions of section 3(e) through (i), the article is deemed to be a banned hazardous substance until a rulemaking proceeding is completed.

Since the imminent hazard determination causes the product to be a banned hazardous substance until the Commission completes its rulemaking, the publication of such determination immediately prohibits all sale and distribution of the product in commerce. Until the rulemaking ends, the Commission may enforce such ban by seeking seizures, injunctions, and criminal penalties.[174]

Section 12 of the CPSA defines an imminently hazardous consumer product as one that presents an imminent and unreasonable risk of death, serious illness or severe personal injury. Although the statute does not define "imminent," the committee finds that injury and death data currently in the Commission's possession supports a finding that ATV's present an imminent and unreasonable risk of death, serious illness or severe personal injury. This finding of unreasonable risk takes into account all of the factors involved in the balancing test previously discussed in this report to arrive at this conclusion.

While the term "imminent hazard" is not defined in the FHSA, the Food and Drug Administration (when it administered the FHSA) issued a regulation defining the term.[175] This regulation states:

> Within the meaning of the Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substance Act, an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat or danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The "imminent hazard" may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to es-

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[172] Ibid.
[173] ANPR, p. 23142.
[174] Ibid.; 15 U.S.C. 1265, 1267.
[175] This regulation is still in effect by virtue of section 30(e) of the CPSA, 15 U.S.C. 2079(e)(2).

> tablish that an "imminent hazard" of such occurrence exists.
>
> (b) In exercising his judgment on whether an "imminent hazard" exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.[176]

The term "imminent hazard," however, is used in other statutes. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, 7 U.S.C. 135–136), administered by the Environmental Protection Agency (EPA), provides that the Administrator of EPA may suspend registration of a pesticide if it presents an "imminent hazard." The term "imminent hazard" is defined in FIFRA as "the situation which exists when the continued use of a pesticide during the time required for cancellation proceedings would be likely to result in unreasonable adverse effects on the environment."[177]

The Federal Food, Drug and Cosmetic Act (FDCA, 21 U.S.C. 355) contains a provision similar to the imminent hazard provision of FIFRA. The provision is part of the section relating to withdrawal of a "new drug application" on the basis of findings that a drug is unsafe or ineffective, that the information contained in the application proves to be untrue or other grounds. The "imminent hazard" provision permits the Secretary to suspend approval immediately if he finds that there is an "imminent hazard to the public health." The legislative history of this provision states that:

> An "imminent hazard to the public health" would exist when the evidence before the Secretary shows that a new drug is so unsafe as to create a public health situation which must be corrected immediately, and cannot be permitted to continue while a hearing is being held. The committee contemplates that this power would be exercised only in the exceptional case of an emergency which does not permit the Secretary to correct it by other means. S. Rep. No. 1744, 87th Cong. 2nd Sess. (1962)

The Occupational Safety and Health Act (OSHA, 29 U.S.C. 662) contains a provision similar to section 12 of the CPSA. The Secretary (of Labor) may petition a district court for an injunction or temporary restraining order to restrain conditions or practices presenting an "imminent danger." The phrase is defined in the statute to mean "a danger . . . which could reasonably be expected to cause death or serious physical harm immediately or before the imminence of such danger can be eliminated through enforcement procedures otherwise provided by the act." 29 U.S.C. § 662(a).

In sum, in most statutes the imminent hazard authority can be exercised when there is a significant danger to the public health which cannot be allowed to continue during the pendency of a hearing or rulemaking proceeding. The committee finds that an "imminent hazard" exists in the case of continued ATV sales because it finds that there is a significant danger to the public health which cannot be allowed to continue.

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[176] 21 C.F.R. § 3.73 (1974).
[177] 7 U.S.C. § 136(l).

(d) Dissemination of safety information

Under sections 2 and 5 of the CPSA,[178] the Commission may disseminate to the public information concerning the risks of injury associated with ATV's and the steps consumers can take to protect themselves from those risks.

One specific option available to the Commission is the dissemination of comparative safety information such as the results of tests designed to measure safety-related performance characteristics of various models of ATV's and/or their component parts. The purpose of such testing would be to provide a comparative basis for assessing the handling characteristics of various ATV's, as opposed to setting performance criteria. Dissemination of comparative safety information would enable consumers to make informed choices about specific types of ATV's.

Prior to disseminating information to the public, the Commission must comply with the procedures contained in section 6 of the CPSA.[179]

(e) Compulsory process

Should the Commission not obtain necessary information concerning ATV's on a voluntary basis, the agency has statutory authority to issue a special or general order requiring any person to submit in writing, under oath, and within a reasonable time, such reports and answers to questions the Commission may prescribe to carry out a specific regulatory or enforcement function.[180] As long as the questions (or reports) are relevant to a pending regulatory or enforcement inquiry, the CPSC is not limited in the types of information it can request. For example, the Commission could specify questions eliciting information on the marketing, sale, labeling, design or any other type of data concerning ATV's. However, the relevant statutory language (section 27(b) of the CPSA) requires that a special or general order impose the least burden practicable and contain a complete statement of the reasons the Commission requires the information.[181]

This special/general authority cannot be used, however, to require the actual production of documents (as opposed to answers to questions) in the possession or control of an individual or firm. Documents can be obtained through the use of the agency's subpoena authority in sections 27(b)(3). This section authorizes the CPSC to require, by subpoena, the testimony of witnesses and/or the production of "all documentary evidence relating to the execution of its duties."[182]

C. THE RESPONSE OF THE STATES

The States have not dealt with the risk of ATV use in a comprehensive or effective fashion. Because ATV's are intended for off-road use, States have generally refrained from applying age, licensing or training requirements as they do in the case of automobiles

[178] ANPR, p. 23143.
[179] Ibid.; 15 U.S.C. 2055.
[180] 15 U.S.C. 2076(b)(1).
[181] Ibid.
[182] 15 U.S.C. 2076(b)(3).

or motorcyles. The argument has been made that the States have no constitutional authority to regulate the use of a product on non-public land. However, States do have authority to regulate to preserve the public's health and safety, but few have seen fit to do so in the case of ATV's. Accordingly, Federal regulation becomes even more necessary.

According to a recent survey by the SVIA,[183] numerous States have mandated various equipment items (such as lights, brakes, and mufflers) for off-road vehicles, including ATV's. Twenty-five States now require ATV's to be registered, through State departments of motor vehicles or through recreation management agencies. However, in various States (Florida, Indiana, Iowa, Maryland, New Jersey, Pennsylvania, and Vermont) such registration applies only to use of an ATV on public lands. In two of the three States (Indiana and New Jersey) as well as in other States (Delaware, Maine, Michigan, New York, Washington, and Wisconsin) registration of the vehicle is not required if it is being used in certain authorized events. Only eight States (Connecticut, Indiana, Maryland, New Hampshire, North Dakota, Ohio, Oregon, and Rhode Island) require a motor vehicle operator's license as a prerequisite for driving an ATV. Yet, not even these States require a license under all circumstances. In fact, three of these eight States (Maryland, Ohio, and Oregon) generally only require a license while riding on public lands.

Less than half of the States (23) set a minimum user age for ATV operation. Yet, in 15 of these States the respective age restriction (ranging from 12 to 16 years old) does not apply if the youngster is being supervised. In other States which specify age limitations, the restriction is waived if the rider has a safety certificate or the restriction applies only when the rider is on public lands. Only Iowa and North Dakota appear to have set definitive age limitations of 12 and 16, respectively.

The SVIA has developed proposed model ATV safety legislation for States to analyze and adopt. This legislation which focuses on ATV use on public lands, calls for:

(1) Registration of an ATV if the vehicle is used on public lands;

(2) Prohibition against minors registering an ATV;

(3) Fees for registration to be credited to an ATV account which will help fund (i) ATV-related safety education, training and skills demonstrations; (ii) acquisition, maintenance, and development of vehicle trails and use areas; and (iii) administration, implementation and enforcement of this legislation;

(4) Authority to be granted to a State official to set rules relating to ATV's, including (i) registration of these vehicles and display of registration numbers; (ii) ATV use which affects fish and game resources; (ii) ATV use which affects public lands and waters; and (iv) uniform signs to be used by the State, counties, towns, and cities to control, direct or regulate the operation and use of ATV's;

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[183] The information in this section concerning State laws is based on data compiled by the Specialty Vehicle Institute of America.

(5) Establishment and implementation of a comprehensive ATV safety education, training, and skills demonstration program by the State official named above, which provides for (i) issuance of safety certificates to operators of all ages who successfully complete the training or pass the knowledge and skills test established under the program; and (ii) development of programs to certify ATV-safety instructors, clubs, associations and the like to act for the State official in conducting classes, examinations or issuing safety certificates;

(6) Determination of age 14 as the minimum age for operation of an ATV on public lands within a State unless the individual (i) is taking a prescribed safety course; (ii) is under the direct supervision of an adult holding a safety certificate; (iii) already holds a safety certificate and is accompanied by and under the direct supervision of a parent, guardian or other adult authorized by the parent or guardian;

(7) Determination that persons age 14 or older shall operate an ATV on public lands within a State only if the individual (i) is taking a prescribed ATV-safety course; or (ii) is under the direct supervision of an adult who holds a safety certificate or (iii) already holds a safety certificate;

(8) Requirement for dealers to distribute ATV-safety information to ATV purchasers;

(9) Requirements for (i) noncareless and nonreckless operation of an ATV; (ii) use of helmet and eye protection; (iii) no carrying of passengers while an ATV is being operated on public lands; and (iv) no use of ATV while the operator is under the influence of alcohol or the influence of a controlled substance or the influence of prescription or nonprescription drugs which impair vision or motor coordination or the influence of any combination of these agents;

(10) Equipment requirements for (i) headlamp and taillamp; (ii) brake system; (iii) muffler; and (iv) spark arrestor; and

(11) Notice as required by State law by the operator of each ATV involved in an accident resulting in a death or an injury necessitating treatment by a physician.

The model legislation has not been adopted completely by any State.

APPENDIX

CONGRESSIONAL RESEARCH SERVICE,
THE LIBRARY OF CONGRESS,
Washington, DC, March 28, 1986.

To: House Government Operations Committee, Subcommittee on Commerce, Consumer, and Monetary Affairs Attention: Ted Jacobs.
From: Migdon Segal M.S., Analyst in Transportation Technology, Science Policy Research Division.
Subject: Consumer product recalls.

This responds to your request of March 7 for information on recent consumer product recalls. We understand that this information is needed in connection with your preparation of a committee report on all-terrain vehicles (ATV's).

Our response, in the form of a "CRS white paper," was prepared by five CRS analysts from the Science Policy Research Division. I prepared the section on the Ford Pinto recall. The section on "TRIS" was written by Michael Simpson. Irene Stith-Coleman wrote the section on the "Dalkon Shield." Pamela Smith wrote the section on Rely tampons. Blanchard Randall IV prepared the section on pharmaceuticals.

Each of these recalls represents a unique situation, and comparisons between them, or between these recalls and a possible recall of all-terrain vehicles, would be difficult. From the congressional testimony and press accounts, an ATV recall would seem to resemble the TRIS, Dalkon Shield, Rely, and pharmaceutical recalls more than the Ford Pinto, since the ATV would presumably be destroyed (that is, would not be fixable) as in those four situations, not repaired and returned to service as with the Pinto.

In addition to the "white paper," we have included selected articles on the five topics covered. If we may be of further assistance, please do not hesitate to call.

Enclosure.

CONSUMER PRODUCT RECALLS DURING THE PAST DECADE: SELECTED SUMMARIES

THE FORD PINTO

The Ford Pinto was a compact automobile produced by the Ford Motor Company, beginning in 1970 (with the 1971 model year), and ending in 1980. In 1978, pre-1977 model year Pintos were recalled by Ford, following a determination by the National Highway Traffic Safety Administration (NHTSA) that the vehicle was unsafe be-

cause the fuel tank could explode when the vehicle was hit from the rear.

A total of 37 deaths attributed to the faulty fuel tank design were estimated to have taken place during 1975–78, the years immediately preceding the recall. An independent researcher [1] extrapolated this total to arrive at a total of 61 deaths for the time period 1970–78. The number of injuries was assumed by the researcher to be roughly the same as the number of deaths, since other studies had shown that in motor vehicle fire accidents, half the injuries would normally result in fatalities.

Roughly 1.4 million Pintos were estimated to be operating in 1978, when Ford sent out its recall notices. By mid-1979 approximately 800,000 Pintos had been modified in response to the recall. (This is apparently a normal rate of response to an automotive recall.) The cost of the recall to Ford was estimated at perhaps $10 million, divided about equally between parts and labor.[2]

TRIS

The U.S. Consumer Product Safety Commission (CPSC) requires that all children's sleepwear through size 14, as well as yard goods intended for use in sleepwear, be flame resistant, i.e., must stop burning after the fire source is removed. Today, almost all U.S. manufacturers satisfy the requirement by using inherently flame-resistant fibers or fabric construction, not by adding flame-retardant chemicals to the fabric. But in the 1970s, as much as 10 million pounds of the chemical tris (2,3 dibromopropyl) phosphate, known generally as "TRIS", were added each year as a flame retardant to various materials, mostly for use in children's sleepwear. TRIS, which accounted for five to ten percent of the weight of the new garments, could have been ingested by a child chewing on a sleeve or other part of the garment. The National Cancer Institute's carcinogen bioassay program determined that TRIS caused tumors in rats and mice. Further, it was found that dibromochloropropane, an impurity of TRIS, also cause cancer in rats and mice. Resultantly, on April 8, 1977, the CPSC banned the use of TRIS as a flame-retardant for children's wearing apparel. A program for recalling TRIS-treated apparel and fabric was established, and the export of such items was prohibited by May 5, 1978. The CPSC supervised the destruction of those items submitted for destruction.

There were legislative efforts to provide compensation for losses sustained by producers, processors, manufacturers, or other persons resulting from the ban on TRIS-treated children's sleepwear, but none became law. The bill that progressed furthest was S. 823. One strong argument against such compensation was that illegal profits could be realized by those unscrupulous enough to continue selling the banned goods. Some new TRIS-treated garments are still in storage, and some have been sold as recently as 1981. Supporters of compensation claimed that the cost to the United States would have been between 40 and 150 million dollars in 1981, depending upon the details of eligibility.

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[1] Dardis, R., and C. Zent. The Economics of the Pinot Recall. Journal of Consumer Affairs, v. 16, No. 2, winter 1982. p. 261-277.

[2] Ibid.

The ban, recall, and prohibition of exportation actions were taken without conclusive data regarding TRIS' carcinogenicity or mutagenicity to humans. There are no known past or ongoing studies to conclusively demonstrate TRIS' carcinogenicity or mutagenicity in humans.

MICHAEL SIMPSON.

THE DALKON SHIELD

The Dalkon Shield, a contraceptive intrauterine device (IUD), was manufactured by A.H. Robins Company (Richmond, Va.). This IUD was marketed in the United States from 1970 to 1974, when A.H. Robins took it off the market, following reports of a number of medical problems associated with its use (the Dalkon Shield was also marketed in 80 other countries). By September 1974, the Dalkon Shield was linked, as a causative factor, to 209 septic abortions, 11 maternal deaths from sepsis (caused by invading bacteria), and serious infections. A.H. Robins stopped selling the Dalkon Shield in 1974, after selling an estimated 4.5 million Dalkon Shields around the world, but did not issue a recall.

In 1980, A.H. Robins sent letters to physicians in the U.S. urging them to remove the Dalkon Shield from users. The Food and Drug Administration (FDA) issued a similar recommendation in 1983. To date, as many as 20 deaths have been associated with the Dalkon Shield, and A.H. Robins has settled more than 9,000 cases for $378 million (plus legal expenses of $107 million), for problems ranging from infections to death. In addition, cases are pending and are still being filed.[1] [2] [3]

IRENE STITH-COLEMAN.

RELY TAMPONS

In the late 1970s, a life-threatening multisystem illness called toxic shock syndrome (TSS) began to be reported in the medical literature. By mid-1980, when the number of cases suddenly started to increase, it had attracted the attention of the lay press and the public. The disease was characterized by sudden high fever, vomiting, diarrhea, a sunburn-like rash, and dangerously low blood pressure, and was fatal in about five percent of cases. It was found primarily in previously healthy young women who were menstruating. The syndrome was known to be associated with the presence of a bacterium called *Staphylococcus aureus,* which produces a toxin, but the actual cause of the illness was not known.

By early summer 1980, a link between the disorder and the use of tampons had been made. In mid-September, the Center for Disease Control (CDC) announced the preliminary results of a study indicating that use of Rely brand tampons, a product of Procter & Gamble Company, might increase risk of TSS more than other brands. At that time, CDC had received reports of 299 cases of TSS, 285 of them in women. Ninety-five percent of the cases in women

[1] Adams, J. Who Stood to Gain On the Dalkon Shield? New Scientist, Sept. 26, 1985. p. 74-75.
[2] Benson, M.D., R.C. (ed.) Current Obstetric and Gynecologic Diagnosis and Treatment. Lange Med. Publ. (Los Altos, Calif.), 1984. p. 541.
[3] Alexander, C.P. et. al. Robins Runs for Shelter. Time, Sept. 2, 1985. p. 32-33.

had occurred during their menstrual period. Twenty-five deaths had been attributed to toxic shock syndrome since 1975, all of them among women. In the study reported by CDC, 50 women who had developed TSS during July or August 1980 were questioned about their tampon use; 71 percent of them had used Rely, compared to 26 percent of matched control women who had not contracted the disease.

The Food and Drug Administration, in announcing the results of this study, said that it was considering whether the new information was sufficient to warrant taking a regulatory action against Rely or any other brand of tampons. On September 22, 1980, Procter & Gamble voluntarily withdrew Rely brand tampons from the market. According to the New York Times, the company's loss from the recall was about $75 million.[1]

PAMELA SMITH.

PRESCRIPTION AND OVER-THE-COUNTER DRUG PRODUCTS

During the past few years there have been few, if any, Food and Drug Administration (FDA) required market withdrawals of previously approved prescription and over-the-counter pharmaceuticals. The industry has voluntarily removed some products following reports of adverse drug reactions, some of which involved fatalities.

In 1980, Smith, Kline & French suspended sales of Selacryn, a high blood pressure medication, following reports of liver damage and death. In 1982, after only a few short months on the market, Eli Lilly suspended sales of its new arthritis drug Oraflex. Oraflex use was associated with over 3,00 adverse reaction reports including more than sixty deaths. At the time Lilly was projecting yearly sales of Oraflex to be in the $100 million range.

On March 4, 1983, McNeil voluntarily withdrew its new drug Zomax, a nonsteroidal anti-inflammatory analgesic. Sales of Zomax the previous year were reportedly near $90 million.

Johnson & Johnson, the parent company of McNeil, has now had to withstand two major tampering episodes involving its over-the-counter drug Tylenol. In September of 1982 the Cook County (Illinois) Medical Examiner's Office advised McNeil Consumer Products Company that seven deaths due to cyanide poisoning had occurred in the northwestern suburbs of Chicago. Early in 1983 McNeil sued its insurers for about $117 million to cover the costs of the company's nationwide recall of its Tylenol product.

In February of 1986 Johnson & Johnson was again confronted with another instance of Tylenol capsule tampering resulting in one death. The company made the decision to recall all of its capsuled products at a cost that will exceed hundreds of millions of dollars.

[1] U.S. Study Aims at Assessing Number of Toxic Shock Cases. New York Times, Dec. 2, 1985. p. B6.

Each of these examples involved input and dialog with FDA officials. However, the agency has not taken action such as invoking the "imminent hazard" clause of the Federal Food, Drug, and Cosmetic Act. Such an invocation would order a product to be removed from the market rather than let a corporation make a voluntary withdrawal or recall.

BLANCHARD RANDALL IV.

ADDITIONAL VIEWS OF HON. BEN ERDREICH

I would like to commend the Committee, Subcommittee, and the Chairmen. Mr. Brooks and Mr. Barnard, for their efforts to bring about this Report, "Consumer Product Safety Commission's Response to Hazards of Three-Wheel All-Terrain Vehicles (ATV's)." I attended hearings last spring, held by Subcommittee Chairman Barnard, and found that the safety questions surrounding the use of ATV's are indeed serious. I would also like to express my appreciation to Dr. Philip Fine from my district, the co-director of the Spinal Cord Injury Care System at the University of Alabama in Birmingham, for his testimony during those hearings.

The Report issued by the Committee is timely and certainly accurate in stating that three-wheel all-terrain vehicles are dangerous. There have been many serious injuries and 415 documented fatalities associated with ATV use since 1982. A Consumer Product Safety Commission staff review has revealed that 191 of these deaths, or 46 percent, were under 16 years of age.

I certainly agree with the Committee's findings that manufacturers should include safety equipment, such as a helmet, with the price of the ATV. Manufacturers should also stress the need for safe riding practices in all ATV owner manuals and should advise riders to wear a helmet, boots, gloves, and other protective gear. However, several of the recommendations put forth by the Committee are of concern to me in light of the fact that the Consumer Product Safety Commission has yet to issue its findings on the standards associated with the use of ATV's.

I am concerned that the recommendations for a Congressional ban on ATV's and a halt of current production and sale of ATV's, may be premature and may extend beyond the proper legislative oversight role of the Committee and the Congress as a whole. While Congress should certainly exercise its oversight authority of Federal agencies, and especially one charged with ensuring public safety, I am not certain that, at this point in time, the Committee's substantive recommendations for legislative action, as opposed to agency action, should be made before those of the Federal agency involved, the Consumer Product Safety Commission, which has assured our Committee that it will issue its own Report and recommendations early this fall.

BEN ERDREICH.

DISSENTING VIEWS OF HON. LARRY E. CRAIG, HON. FRANK HORTON, HON. THOMAS N. KINDNESS, HON. ROBERT S. WALKER, HON. ALFRED A. (AL) McCANDLESS, HON. HOWARD C. NIELSON, HON. JIM SAXTON, HON. PATRICK L. SWINDALL, HON. THOMAS D. (TOM) DELAY, HON. RICHARD K. ARMEY, HON. JIM LIGHTFOOT, HON. JOHN R. MILLER, AND HON. BEAU BOULTER

Subjectivism is defined as a doctrine in which individual feeling or apprehension is the ultimate criterion of the good and right. The Committee's report, "Consumer Product Safety Commission's Response to Hazards of All-Terrain Vehicles (ATVs)," sets forth subjective conclusions rather than factual findings. Regrettably, the Committee is simply substituting its own policy views for the substantive investigatory and decisionmaking function assigned to the Consumer Product Safety Commission (CPSC), and is short-circuiting a technically complex regulatory investigation. Regardless of where strongly held personal views come down on this very serious issue, if the process is violated in the interest of opportunistic expediency, then the outcome can be nothing other than suspect.

Obviously, we have no other choice but to suspect the subjectivism in the report. In short, we find the report to be extremely premature, in many cases inaccurate and misleading, and incomplete. Equally, we are appalled at the recommendations to ban and recall all three wheeled ATVs in the United States without having the factual data to justifiably merit such an action. It is most unfortunate that "fictional writing," which could affect a $1.5 billion American industry and 38,000 jobs, has received the stamp of approval from the House Committee on Governmental Operations.

For the Committee to adopt this incomplete report which excludes the findings and recommendations of an 18 month, $2 million investigation of ATVs by the CPSC was profoundly foolhardy at best and a classic example of bad government at worst. Due process of law has been waived aside by the Committee, fairness has been scoffed at and ignorance has triumphed over righteousness.

In so doing, the adoption of this report now taints a formerly unadulterated and independent CPSC ATV investigation. Under a Congressional threat of "ban them or Congress will do it for you", the Committee has seriously jeopardized the ability of the CPSC to take, if necessary, legal action against any ATV manufacturer in a court of law. In our attempt to do right, we may have done very wrong.

Specifically, we take strong exception to the following findings and statements contained within the report. Most of these findings and statements appear to form the foundation on which the report is based and its ill-conceived recommendations contrived.

First:

> ATV-related injuries are substantially higher than proportionate figures for minibikes/trail bikes and snowmobiles which are similar off-road recreational vehicles.

This is just one example of the report's use of outdated, misleading, and self-serving information. It is misleading because it fails to adjust the relative frequency of use for ATVs, snowmobiles, and minibikes/trail bikes. One rides a snowmobile when there is snow on the ground, which means at the most three to four months in some parts of the country. One can ride an ATV 365 days per year. New information obtained by the CPSC shows that there are 4.5 injuries per 1,000 vehicles in use for ATVs, 7.9–11.9 injuries per 1000 minibikes/trailbikes and 8.5–12.7 injuries per 1000 snowmobiles. Will this new information cause Congress to ban snowmobiles and trail bikes next?

Second:

> In the meantime, deaths and injuries continue to mount with neither the Commission nor the industry acting in a meaningful way to lessen the hazards associated with ATV use.

On the contrary, the CPSC has been very aggressive in seeking a solution to the ATV problem. They are proceeding in the manner dictated by law and established by Congress. When the CPSC unanimously adopted its seven point ATV action plan on April 3, 1985, it set September 30, 1986, as the date its ATV Task Force would submit its final report on ATVs complete with recommendations as to what remedial action or actions the Commission should take. There were several reasons for the selection of this date, the most notable being that the engineering, epidemiological, medical and human factors analyses necessary to arrive at a reasonable and responsible decision were expected to take considerable time and effort. This type of information, and not just raw numbers, is essential if the CPSC is to determine both the causes of ATV related accidents and the best means of prevention or mitigation.

In fact, this is the most ambitious time frame (18 months) for any major project in the agency's history. Similar complex projects, such as investigations of chain saws, gas space heaters, and lawn mowers have typically taken the agency 4–5 years to complete.

In fiscal year 1986, the CPSC will spend over $1.1 million on their ATV investigation which includes the expenditure of over $40,000 in television Public Service Announcements regarding ATV safety.

The Specialty Vehicle Institute of America (SVIA), which represents the makers of ATVs, has been working diligently with the CPSC to establish voluntary ATV safety standards. New model ATVs will contain several large warning labels, including one on recommended age limits for youthful operators. Several key operating controls such as throttle controls, parking brakes, engine stop switches, flag pole brackets, clutch levers, gear shift controls, etc., will be commonly located on all ATVs regardless of the manufacturer. In the meantime, the SVIA continues to train hundreds of ATV rider instructors, who in turn train thousands of individual ATV enthusiasts.

For this report to state that the CPSC and the manufacturers are not acting to lessen the hazards associated with ATVs is simply not true. What is true, however, is the fact that the efforts by the CPSC and the manufacturers are having an impact on the number of injuries as reflected by the report's statement, "* * * the annual estimate of ATV-related injuries appears to be leveling off * * *". This statement is inconsistent with the Committee's finding that, "death and injuries continue to mount * * *".

Third:

> The committee is firmly convinced that sufficient data has already been disclosed and sufficient analysis performed to justify immediate enforcement action by the CPSC.

Clearly the hearing record in itself disputes such a statement and finding. All of the CPSC commissioners who submitted testimony before the May 21, 1985 hearing on ATVs stated that the CPSC did not have the data or hazard analysis to substantiate a ban or recall on ATVs. In addition, Joseph Greensher, M.D., chairman of the American Academy of Pediatrics, Committee on Accident Prevention and Poison Prevention, when asked if he would advocate the government banning ATVs from the market, stated, "No, sir, not with the present data that we have." Philip R. Fine, co-director of the Spinal Cord Injury Care System at the University of Alabama, concurred with Dr. Greensher's statement, as did the General Counsel of the CPSC. It is most unfortunate that the committee has ignored these most valuable observations.

Fourth:

> Interim reports to the Commission by staff working on the ATV matter make it clear that the staff's final report will only substantiate and expand the basic data already known.

Since the CPSC began its official investigation of ATVs in April 1985, the CPSC's ATV Task Force has provided the Commissioners one principal interim report. According to the CPSC, the information contained in the January 1986 interim report, "tend to confirm the need for information and education on safe operating practices, for driver training, and for additional statistical, engineering, human factors and medical evaluation of factors associated with ATV accidents." At no time did the report recommend a ban or recall of ATVs. When the Committee makes such a superfluous and prejudicial statement regarding the outcome of the CPSC's final report, without having the accurate data, it impairs its ability to make fair and objective decisions.

Fifth:

> * * * no evidence was presented to the committee that would establish a cause and effect relationship between large scale rider misbehavior and negligence, on the one hand, and the mounting toll of deaths and injuries, on the other.

This astonishing finding represents a hear-no-evil, see-no-evil attitude of the committee. The January 1986 interim report issued by

the CPSC, and based on 318 telephone interviews with ATV accident cases, revealed that 35 percent of the accidents involved practices that the ATV manufacturers warned against. The CPSC report also indicated that 56 percent of the accident drivers wore no protective equipment. In addition, the committee hearing record contains a study concerning ATV injuries and deaths in Alaska. At the time of the hearing, this report was the only official epidemiological study in the nation. It was conducted jointly by the State of Alaska's Division of Public Health and the Centers for Disease Control. This report clearly identified excessive alcohol, rider inattention and inexperience, excessive speed, and ineffective helmet use, as the major reasons for the ATVJ-related injuries in Alaska.

Here as in the previous examples, the committee report interposes deliberate misinterpretation for reliable facts which further destroys the credibility of this report. Rider misuse *is*—contrary to the committee's finding—a major factor involved with ATV-related accidents, injuries, and deaths.

We share our colleagues concern over the number of ATV-related injuries. We are equally concerned, however, about the 1,000 deaths per year related to bicycle accidents, and an equal number of boating deaths. On the average there are ten accidental deaths and nearly 1000 disabling injuries every hour of the day during the year in the United States. Despite the best intentions of Congress and federal or state regulators, we have not, cannot, and will not produce, either through legislation or regulation, risk-free society.

A congressional mandate to the CPSC requiring an immediate ban and recall of ATV is the most severe form of action this body could have taken. In order to justify such extremism, the committee should have been able to demonstrate that the end justifies the means. The committee should have been able to prove that the elimination of a $1.5 billion American industry and nearly 38,000 American jobs was the best possible solution to address this issue. And finally, the committee should have been prepared to show that the engineering, epidemiological, medical, and human factors data used to formulate this report's findings and recommendations were factual reflections of current CPSC information. Unfortunately, it did not. The foundation of support for this report rests on shakey ground which will surely crumble before the Halls of Justice. Therefore, we strongly oppose this report in the strongest terms possible.

Finally, we believe that a note of caution should be expressed to those who may attempt to use this report in litigation against any ATV-related industry. For the reason enumerated above, we believe the report is wrong and without merit. Justice would not be served by those who attempt to convince a court of law or jury that this report and its conclusions are the reflection of the Congress as a whole.

LARRY E. CRAIG.
FRANK HORTON.
TOM KINDNESS.
ROBERT WALKER.
AL MCCANDLESS.
HOWARD C. NIELSON.
H. JAMES SAXTON.
PAT SWINDALL.
TOM DELAY.
DICK ARMEY.
JIM LIGHTFOOT.
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